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DMSO: NEW HOPE FOR ARTHRITIS?

HEARING

BEFORE THE

SELECT COMMITTEE ON AGING
HOUSE OF REPRESENTATIVES

NINETY-SIXTH CONGRESS

SECOND SESSION

MARCH 24, 1980

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DMSO: NEW HOPE FOR ARTHRITIS?

MONDAY, MARCH 24, 1980

HOUSE OF REPRESENTATIVES,
SELECT COMMITTEE ON AGING,
Washington, D.C.

The committee met, pursuant to notice, at 10 a.m., in room 1302, Longworth House Office Building, Hon. Claude Pepper (chairman of the committee) presiding.

Members present: Representatives Pepper of Florida, Bonker of Washington, Ford of Tennessee, Oakar of Ohio, Lloyd of California, Mica of Florida, Hopkins of Kentucky, and Drinan of Massachusetts.

Staff present: Charles H. Edwards III, chief of staff; Yosef Riemer, deputy chief of staff; Val J. Halamandaris, senior counsel; David Holton, chief investigator; Kathy Gardner, professional staff member; Nancy Smythe, investigative researcher; Marie C. Brown, executive secretary; Molly Clark, secretary; Henry Hicks, professional staff member; Nancy Hobbs, minority staff director, Subcommittee on Retirement Income and Employment; Larry Parkinson, minority staff director, Subcommittee on Health and Long-Term Care; Walter Guntharp, minority staff director, full committee; and Bob Branand, minority general counsel, full committee.

OPENING STATEMENT OF CHAIRMAN CLAUDE PEPPER

The CHAIRMAN. The committee will come to order, please.

The subject of this hearing this morning is a matter that may be of great importance for a great many millions of people in our country.

Back in the late forties when I was a member of what we over here call the other body, the Senate, I was then very painfully aware, although not personally, fortunately, of the pain inflicted upon millions of Americans by arthritis, bursitis, and rheumatism. I was the principal author of the bill which resulted in the establishment of the National Institute on Arthritis, Metabolism, and Digestive Diseases.

Arthritis is not a new interest on my part. I have been trying to help find something that will give relief to millions of our fellow citizens, most of them elderly people, from the great pain and deformity which it causes.

So when we heard from a number of sources about this drug dimethyl sulfoxide (DMSO), that Dr. Jacob has provided the initiative for, we were very keenly interested. I know an army of millions out there would rise up and call us blessed if we could give them even a measure of relief from the pain that they experience daily and nightly from arthritis.

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[See app. 1, p. 99, for staff briefing memo on arthritis and DMSO.]

This drug has been used for many years by veterinarians. We contacted hundreds of veterinarians and about 70 percent of the veterinarians contacted have been using it, and about 95 percent of them responded that they had found its use remarkably satisfactory in dealing with animals that they were treating for arthritis, inflammation, swelling, and other disorders.

[See apps. 2-6 for results of committee's questionnaires and letters from foreign health organizations and officers, pp. 103-117.]

The Food and Drug Administration has not so far approved the drug for general use in humans. We want to know why they have not approved it if, as has been claimed, it shows efficacy or the great promise of efficacy. Have they exercised the due diligence in trying to see that adequate research was done to determine if it could be safe for use upon humans?

We are simply concerned about doing what we can to help people inflicted with the painful illness of arthritis, some of whom have had distortions in their body posture, or hands on account of it. We are anxious to see if there is any way that we can be helpful in promoting this or any other drug that will be meaningful to the people who suffer from that illness.

[The prepared statement follows:]

PREPARED STATEMENT OF CHAIRMAN CLAUDE PEPPER

Good morning ladies and gentlemen. I would like to welcome you to this hearing by the House Select Committee on Aging. Today, we want to hear from expert witnesses about the possible benefits of the drug, dimethyl sulfoxide—widely known as DMSO. The drug, on one hand, is heralded as a new wonder drug and, on the other hand, decried as a quack remedy. We intend to learn the truth.

DMSO is a by-product from the manufacture of paper. In refined form, it is applied directly to the skin in either a liquid or ointment form.

The drug is said to be very effective in reducing pain, swelling, inflammation and other symptoms of arthritis. Since there are 31 million people with arthritis, most of them elderly, we are very interested in the potential of this drug.

The drug has its critics who label it as an unproven remedy. The Food and Drug Administration has not approved the drug for general use in humans. The drug, however, is legal for veterinary purposes and one specific medical condition in humans.

This morning we will hear from both sides on this important question. We hope to learn what, if anything, the Congress should be doing about DMSO and Federal laws which relate to drug testing.

In an effort to learn more about DMSO, we have sent questionnaires to international health experts in several countries where DMSO is legal for human use. We have also sent questionnaires to rheumatologists in the United States, and to team physicians with many pro-sports teams. Finally, we sent questionnaires to veterinarians to learn from their experience in treating animals with DMSO

Not many rheumatologists reported they had experience with the drug. Those who had were about evenly divided on whether it should be legalized for human use. Veterinarians were overwhelmingly positive about their experience. Fully 70 percent of the veterinarians had used it and 95 percent of this number claimed the drug was effective. Eighty percent of them said it should be legalized for human use.

Team physicians from American and Canadian pro-sports teams were reluctant to talk about their use of the illegal drug. Several of them called our staff to confirm the widespread use of the drug in pro-sports and to give us the names of people willing to talk about it.

We have a distinguished list of witnesses here this morning and I look forward to hearing from both proponents and opponents of the drug.

The CHAIRMAN. We have two of our colleagues here this morning who have been kind enough to come to give us some evidence that they have acquired by experience in the use of this drug.

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Before I call on our first witness, I will call on my distinguished friends and colleagues, Mr. Lloyd, and Mr. Ford.

Mr. Lloyd, do you have any statement to make?

STATEMENT OF REPRESENTATIVE JIM LLOYD

Mr. LLOYD. Thank you very much, Mr. Chairman.

Obviously, there is a great deal of interest in this drug, as you have indicated. If indeed it can provide relief, then we should really consider it. There is reluctance on the part of the federal agencies to allow people to have these drugs if they have not been proven positive in the medical clinics. However, it would appear to me that if an individual is suffering and they believe that a given drug will somehow give them relief in a catastrophic illness, and certainly arthritis is such an illness, then we should certainly go forward to do that.

I am glad that you are holding these hearings, Mr. Chairman. I also note that last night I watched "60 Minutes," a segment of which dealt with this drug. I am very much pleased to be a part of your committee, sir.

The CHAIRMAN. Thank you, Mr. Lloyd. I am glad that you referred to the "60 Minutes" program last evening. Many of you may have seen it. We are taking steps to get a transcript of that program. I would like to commend "60 Minutes," Mike Wallace, Producer Marion Goldman, and Assistant Producer Janet Harshman for their work.

Without objection, the material in that program will be inserted in the record of this hearing.

[See app. 7, p. 128, for transcript of "60 Minutes" program.]

The CHAIRMAN. Now, another of our distinguished colleagues, the Hon. Harold Ford.

STATEMENT OF REPRESENTATIVE HAROLD E. FORD

Mr. FORD. I want to thank you very much, Mr. Chairman.

I, too, am glad to participate with you and members of this committee this morning because when I think of 31 million Americans who suffer from arthritis, it is obvious that this committee should in fact look at both sides of the issue and determine what this committee should do or what action the Congress should take at this point in being under the very able and capable leadership of you, Mr. Pepper. It is obvious that we will in fact, after studying the issue, move forward in a real positive way in the Congress.

Again, I thank you and I look forward to hearing my colleagues testify before the committee and others who will appear before this committee today. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you very much, Mr. Ford. We appreciate your fine statement.

I would like to submit for the record at this point, a prepared statement of Representative Edward R. Roybal. Hearing no objections, it is so ordered.

[The prepared statement of Representative Edward R. Roybal follows:]

PREPARED STATEMENT BY REPRESENTATIVE EDWARD R. ROYBAL

The purpose of this hearing is to provide testimony as to the medicinal potential of DMSO (dimethyl sulfoxide) in the treatment of arthritis and other bodily ail-

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ments. I hope the proponents will enlighten this committee with answers regarding the effectiveness of DMSO. By the same token, I ask the opponents to carefully consider the adverse effects of this drug and try to dispell any myths about DMSO as a miracle drug for the treatment of arthritis.

Given the fact that DMSO has not been thoroughly tested in the laboratory, I urge the Food and Drug Administration to initiate appropriate testing. I also urge those pharmaceutical companies involved in the production of DMSO to conduct scientific tests and provide thorough documentation regarding DMSO. Before any decisions are made as to the future use of DMSO on humans, scientific evidence is needed in order to ascertain beyond a shadow-of-a-doubt that DMSO is relatively safe.

Since a disproportionate number of arthritis victims are older people, this age group is more likely to seek DMSO as an alternative treatment for arthritis. Special attention must be given to this age group in testing DMSO. This includes a thorough analysis of the physiological and chemical changes associated with the aging process and how these changes may alter the effectiveness of DMSO and/or maximize its adverse side-effects. Bodily changes in the later years of life are often attributed to various diseases associated with old age. Therefore, it is of the utmost importance to examine these changes within the context of prescribing a new treatment for a disease such as arthritis which invariably strikes many older persons.

In addition, consumer education as to the availability of DMSO and possible side-effects must be disseminated. Consumer education should include safeguards against those who might otherwise oversimplify the potential benefits of DMSO.

Let us be prudent and not sign off DMSO as a panacea. Only with such prudence can we protect the health of the general public. We also do not want to create a situation like the controversial drug laetrile which has generated litigation and confused the public.

The CHAIRMAN. Now, our first witness is the Hon. Robert Duncan, able Representative in the House of the great State of Oregon, chairman of the Transportation Subcommittee of the House Appropriations Committee, one of the important members of our body. We are delighted that he has come here this morning to give us his experience with respect to DMSO.

STATEMENT OF REPRESENTATIVE ROBERT DUNCAN, A MEMBER OF CONGRESS FROM THE STATE OF OREGON

Mr. DUNCAN. Thank you, Mr. Chairman.

I have appreciated the opportunity to be here. I consider it my prime mission here this morning to introduce Dr. Jacob, the scientist who first observed the amazing qualities of dimethyl sulfoxide. As an Oregon son, I am proud of the work that Dr. Jacob and the university school have done in this field.

Someone told me the other day this is a byproduct of the wood products industry. I said I am proud of the fact that the forests of the State of Oregon are furnishing not only the building materials to house the people of this country, but we also have the potential to use all the tree, including the squeal, and use some of the chemical properties of the timber we grow to bring relief to people afflicted by a wide variety of illnesses.

I served in the Congress, as you know, in a prior incarnation from the Fourth Congressional District. I guess I first met Dr. Jacob and became interested in DMSO at that time. I was influential in setting up one of the first meetings with the FDA and getting the tests lined up to see if it was efficacious to meet the standards.

At that time I remember Dr. Jacob brought with him a distinguished physician from the Cleveland Clinic and the subject matter was scleroderma which Dr. Jacob will describe to you far more

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accurately than I could. There was no other relief for scleroderma in extremities except, on occasion, amputation of the fingers.

It seems to me that in the absence of any evidence of seriously adverse side effects, and in view of the obvious therapeutic value it had in that instance, that it ought to be used. Here we are some 16 years later after that first meeting with scleroderma still not approved as a disease for which DMSO can be used.

There has been some progress made. I want this committee to know that I am sympathetic with the problems that FDA has in operating under a law which we ourselves passed which requires them to find this drug not only efficacious but safe, and I am concerned about the standards of proof that are set up by FDA in order to permit a drug like this to go on the market.

I know they have a narrow line to tread between letting a thalidomide on the market, for instance, and keeping something like DMSO off. I am sympathetic to them.

I thought as I drove in here this morning that we will have serious impact on men's fortunes by a standard of proof which we call a preponderance of the evidence. We will even deprive people of their liberty by a standard called "beyond a reasonable doubt."

But it seems to me that for drugs, and particularly for DMSO, we are demanding a standard of proof that is almost unattainable. In all of these years of use, can we say there are no side effects? No, there is no free lunch in this country. But the side effects are so minimal that one could almost say there are none.

With respect to my own use of it, the most serious side effect is a threatened divorce by my wife because she doesn't like the odor. Dr. Jacob has removed some of the odor and he has masked it in another preparation by a wintergreen flavor.

I asked my wife if she didn't like the wintergreen flavor, and if that wouldn't remove her objections. She said, no. Instead of smelling like the tidal flats at Bayonne, N.J., when the tide is out, she said you now smell like the locker room of the Green Bay Packers. But that odor is infinitesimal compared with the relief.

But the drug has been shown to have good results in so many instances and the people who have used it are so enthusiastic that the scientists downtown naturally, I think, get suspicious about it.

Somebody asked me what it was good for the other day and I said, did your mother give you medicine when you were a kid and you asked what is this for, and she said, take it, it is good for what ails you.

I think I first got a hold of it for my horses. It was good for my horses. It is approved for use in most of Western Europe, the Soviet Union, a lot of countries in South and Central America and in Japan. I obtained some of it from sailor friends of mine from Japan.

I have observed its beneficial effects for arthritis, bursitis, the reduction of swelling and inflammation. I have seen it almost make shingles disappear like a miracle. I have watched it in serious burns on myself and I watched the pain go away in a matter of minutes. I saw that the serious burn barely got pink and never swelled blisters. The doctor will tell you about these things.

With your permission, I will ask you to put my prepared statement in the record.

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I would like to urge you to do what you can. If it is necessary to make some modifications in our law, I would urge you to do that. I don't think it is. The FDA has prescribed protocol after protocol for the testing of this drug. There have been no serious adverse impacts noted on human life or health. It has so many good effects that in my judgment the welfare of the country demands that we either go ahead and approve it for many more uses than it is now approved for or that we lay out once and for all a protocol and commence the testing and get it done so that we know once and for all what the effects of this are and we can get it into the hands of the American people.

I thank you, Senator.

The CHAIRMAN. Without objection, the statement offered by Representative Duncan will be admitted into the record.

[The prepared statement follows:]

PREPARED STATEMENT OF REPRESENTATIVE ROBERT B. DUNCAN

Thank you Senator Pepper for the opportunity to testify this morning before the Select Committee on Aging in consideration of the use of Dimethyl Sulfoxide, DMSO, to treat arthritis. I also appreciate the chance to introduce my good friend from Portland, Oregon, Dr. Stanley Jacob, a pioneer in the development and use of DMSO.

My involvement in the DMSO controversy stretches back many years. When I first came to Congress in the 1960's from Oregon's fourth district, I communicated frequently with the Food and Drug Administration about the then recently discovered medicinal properties of DMSO. In my present reincarnation from the third district, I find myself doing the same thing some 16 years later. Progrss has been made during that period, but it is barely perceptible. DMSO is now, as you know, prescriptive for a troublesome bladder disease, interstitial cystitis. It cannot be prescribed for any other uses on human beings.

DMSO helps alleviate symptoms in many, many ailments. Sophisticated experimental protocols designed by the National Academy of Sciences offer substantial evidence that it is helpful in easing the pain and preventing digital amputation in scleroderma patients. There is evidence that it is effective in reducing intracranial swelling, heretofore virtually untreatable. DMSO exhibits evidence of effectiveness in treating burns and bruises. Studies indicate improvement in retarded and Down's Syndrome children when given DMSO orally. I have used it enthusiastically for several years for troublesome bursitis and am satisfied, beyond any reasonable doubt, that it works, quickly, effectively. The only serious side effect is that Mrs. Duncan can't stand the smell, and even that is being solved.

Today we gather to explore the uses of DMSO in treating arthritis, a disease particularly bothersome and disabling to the elderly. I am no scientist and do not pretend to evaluate its medicinal and therapeutic effects. What I do know, as a lawyer and a legislator, is that the FDA should make it possible for DMSO to reach those suffering the relentless pain of arthritis as soon as possible. I fully understand the cloud hanging over the FDA these many years after the Thalidomide tragedy. We should continue to do everything in our power to keep all Americans safe from such dire consequences.

But try as we might we cannot create, either legislatively or through regulation, a riskless world. Every human endeavor carries with it some probability of injury or death. The probability in most actions is very slight, but it exists. We all know stories of bathtub drownings and choking to death on food. Life is rife with examples of illness, injury, and even death that no amount of regulation or study would have foretold or circumvented.

The FDA requires high standards of proof, nearly impossible to attain, before it allows a drug to be prescriptive. In a court of law, civil cases must be proven by a preponderance of the evidence; in a criminal case, the standard is beyond a reasonable doubt. The FDA requires something beyond the criminal standard. In many instances it seems they require absolute proof, not only of efficacy, but of no negative effects. This requirement is analogous to attempting to prove in court that something did not happen. A good example is trying to prove that a police siren was not turned on. One can call a witness to the stand and have him testify that he did not hear a siren. But that leaves the jury free to draw inferences of a range of other possibilities—the witness could have been asleep, he could have had a radio turned

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up, he could have been on the telephone—all in addition to suggesting that the siren might not have been turned on.

In testing DMSO, the FDA requires proof of no side effects, no danger. Scientists bring up their most compelling evidence; the best science has to offer. Their data shows DMSO to have only the most mild topical, secondary effects, spread over thousands of cases and in many different applications. But the FDA does not move. I have been told that they are satisfied that it works, that the side effects are acceptable, but that they do not know how it works—how it does what it does. If we held Aspirin to the same standard, it most certainly would not be freely available on today's market.

In daily life we all take many risks of varying degrees. It is time for the Food and Drug Administration to lift their standard of absolute proof and allow DMSO, a cheap, effective and safe drug to bring relief to those suffering the nagging, crippling ache of arthritis.

It is my pleasure this morning to introduce Dr. Stanley Jacob of the University of Oregon Health Sciences Center. Dr. Jacob, as you all know, is a nationally known surgeon who has spent most of the last 18 years experimenting with DMSO and studying its effects in many treatment protocols. Dr. Jacob's academic and professional credentials are impeccable. But more important are the energy and commitment he brings to his drive to have DMSO scientifically tested, proven and marketed so that its great therapeutic value is available to help those who need relief from the debilitating symptoms of disease. I only wish we had Stan working on the drive to balance the budget; I am certain that we could alleviate the dreadful symptoms the economy now suffers were he to focus his energies and train his intelligence, energy and ability on financial matters.

The CHAIRMAN. I just want to ask you two questions, Mr. Duncan.

First, did you ever use the drug with respect to arthritis? Do you happen to have any arthritis?

Mr. DUNCAN. No, sir, I do not have arthritis. But I still fancy myself something of an athlete so I am faced with a constant series of strains and bruises. Bursitis is the common predicament as one gets advanced in years and still tries to pretend he is a kid. The results are dramatic.

The CHAIRMAN. The second question is, just for the record and for background for us, you have known Dr. Jacob for a long time evidently?

Mr. DUNCAN. I would guess about 16 years, yes, sir.

The CHAIRMAN. You know him to be a qualified physician and in good repute in the community in which he lives?

Mr. DUNCAN. I had thought those things were almost unnecessary to say. Yes, I certainly do. He is a fine physician, a surgeon. He is a respected member of the faculty of the University of Oregon Medical School. For 16 years he has tried diligently to advance the cause of this drug in which he believes so thoroughly, and because the scientific tests that he has performed have proven to him beyond a doubt that it is safe and efficacious, he has tried to follow the usual protocols of obtaining approval of this drug.

There may indeed be some of his colleagues who would object to his appearing on a television show last night. But at some point people have to do something to break up a logjam of lethargy and disinterest and get something going.

The CHAIRMAN. Mr. Bonker, do you have any questions to ask Representative Duncan?

Mr. BONKER. Mr. Chairman, I have an opening statement I would like to submit for the record and I apologize for being late.

The CHAIRMAN. Without objection your statement will be received.

[The prepared statement of Mr. Bonker follows:]

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PREPARED STATEMENT OF REPRESENTATIVE DON BONKER

Mr. Chairman, I appreciate the opportunity to be here this morning. I enjoyed watching CBS "60 Minutes" last night. They are to be commended for bringing this matter to the attention of the public. I would also commend you, Mr. Chairman, for calling these hearings.

It may be interesting for you to know that I first heard about DMSO some 15 years ago when I was employed as a staff person by then Senator Maureen Neuburger of Oregon. The senator was firmly convinced that DMSO was safe and had important medicinal values. Judging from the "60 Minutes" piece, an increasing number of Americans are coming to the same conclusion.

Mr. Chairman, 16 years is a long time for the public to wait. It seems to me that the controversy surrounding DMSO should have been settled long before this. There should be definitive answers instead of lingering questions. I want to learn today why it has taken the Food and Drug Administration so long to give their approval for the use of this drug as an analgesic, to promote healing in soft tissue injuries, to ease the pain of arthritis and to help cure ulcers on the fingers that are common to a unique disease, scleroderma.

We heard the Director of FDA's Bureau of Drugs tell Mike Wallace last night that DMSO is a safe drug; that there are no serious side effects associated with its use. Indeed, this is obvious or the FDA would not have approved its use in humans for the bladder disease, interstitial cystitis. This leaves only the question of efficacy and it is clear to me that there is overwhelming evidence indicating DMSO would be helpful in those instances that I have mentioned and there is growing evidence that it may be helpful in relieving spinal cord injuries and intracranial pressure.

I want to learn to what extent the FDA's failure to approve this drug for more wider use in humans can be laid to the fact that it is not thought to be patentable and does not have a major drug company as one of its sponsors.

The questions that will be raised in today's hearings have importance that goes beyond DMSO. It appears we have a general drug lag in the United States which has been brought about either by the law that we passed several years ago or by its inappropriate implementation by the FDA. I mean to learn which is the case.

I look forward to hearing today's witnesses.

Thank you.

Mr. BONKER. I guess this is something of a unique issue for Oregon because 16 years ago when I worked for a U.S. Senator from Oregon, Dr. Jacob used to make his frequent trips back to Washington, D.C. to promote this new, immediate, cool discovery and Senator Neuburger at the time became quite an advocate for the cause, as did others in the Oregon delegation.

So now it is 16 years later and Representative Duncan is still here fighting the battle and Dr. Jacob is still making these trips. I just wonder how much longer it is going to take before FDA listens to reason.

I think the hearings today are appropriate. I have very high regard for Bob Duncan and his testimony and also for Dr. Jacob who has been struggling with this issue for so long. Hopefully, some day the FDA will see the light and we can make available this medication on a broader scale.

The CHAIRMAN. Thank you, Mr. Bonker.

Mr. DUNCAN. Mr. Chairman, I might say that while this product I assume thus far has been made with trees that have been grown in the State of Oregon, as Mr. Bonker has at least implicitly recognized, we have no reason beyond parochial pride to believe that the trees grown in the State of Washington would not likewise be useful in producing this drug.

Mr. BONKER. I need to comment on that because my concern is that we are shipping all our trees to Japan.

The CHAIRMAN. Mr. Lloyd?

Mr. LLOYD. Again, I would like to welcome my colleague, Bob Duncan, who has introduced some very fine legislation. I would

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like to confirm the fact that Bob Duncan is a remarkable man when it comes to physical capabilities. I have had the opportunity to participate with him and I think we are very fortunate.

I am very pleased that you made the statement you did today. Let's not lose sight of what it is we are trying to do. All too often, wouldn't you say Mr. Duncan, we get tangled up in our own harness in government and we sometimes prevent good things when in our endeavors to somehow insure that everything will be perfect—maybe we ought to learn how to accept the world as it is. Would you comment on that?

Mr. DUNCAN. I certainly could not agree more. There are trade-offs for anything you want to do. As I said in my statement, there is no free lunch. What we must do is equate the values with the disadvantages and make a decision.

In fairness to the FDA, I don't think it is all their fault. A lot of this problem we have contributed to in the Congress by freezing so many of our laws with absolutes because of good objectives. I think this is true with the NEPA law, clean air and water. I think we have set almost unattainable standards of perfection that are in effect hampering the country's effort to get ahead and survive this difficult period.

Mr. LLOYD. Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Hopkins?

Mr. HOPKINS. Thank you very much, Mr. Chairman. I apologize for my tardiness this morning.

Last night on "60 Minutes" it was noted by an executive from a major drug company that dimethyl sulfoxide, DMSO, would not be a profitable item to market since it is a common chemical solvent, easily and inexpensively produced at about $4 a quart.

Do you share that view, Congressman?

Mr. DUNCAN. I have no evidence that that is so. Perhaps some of the other witnesses would comment on it. I would hesitate to state it in those terms. It might be phrased accurately in these positions as follows:

The patent is joined in by the University of Oregon Medical Schools. I think Dr. Jacob has put any potential earnings he might have in a foundation. I don't really, and would certainly hesitate to say, and don't really believe there is active opposition from people because of the relative ease of obtaining it and its inexpensiveness.

But I would say that if it were an expensive drug and in a capitalistic society if there were an opportunity to make big profits, that there might be substantially greater pressures to get it approved. But I would rather put it in that negative fashion rather than the positive one that you did. I don't know that there is any evidence that there is a malicious conspiracy to keep it off the market.

Mr. HOPKINS. To what extent, Bob, in your opinion, does the lack of interest in developing new therapeutic drugs perhaps by the industry hamper their potential use?

Mr. DUNCAN. I am not sure I would say it is a lack of interest. I think we have so circumscribed this whole process of examining and proving or trying to prove the almost impossible that we have, in effect, discouraged the drug companies from making applications for new drugs.

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This drug, for instance, is on the market in most of the western world. There are other drugs where that is so. I am not saying that our standards ought to be identical with the standards in Western Europe or the Soviet Union. But I am saying that I think that we have, both by our writing of the law and the FDA's interpretation of it, detoured the drug companies in making applications, the terribly expensive protocols that they must go through.

If I am not mistaken, there is another problem. By the time they go through this multiyear process, and here it has taken 16 years, by the time you get a patent, after 17 years your patent time is almost gone. So with all this expense and effort the drug company might find itself with a product in the public domain within a year or two and not even be able to recover its expenses.

Mr. HOPKINS. Thank you.

The CHAIRMAN. Mr. Ford?

Mr. FORD. Thank you, Mr. Chairman.

Again, Mr. Duncan, thank you for appearing before the committee. Fifteen years is a long time. And now to say for the Food and Drug Administration to lift their standards to allow the DMSO to go on the market, what has happened in that 15-year period, Mr. Duncan? Five years ago, what were they saying then? What is new that we can say to the Food and Drug Administration that would change their mind? Have they really absolutely made up their mind, you know, they are concrete on a decision that they are not ready to complete any future studies to see whether the drug would be acceptable on the market or not?

Mr. DUNCAN. No. They keep saying that it needs more testing. Let me correct the record at this point because FDA has approved the use of this drug for interstitial cystitis which is a bladder problem that affects females for the most part. So they have said it is safe for that use.

Now the question, I guess, is its efficacy in this broad range of other illnesses for which it ostensibly has some utility. There they keep saying, well, we don't have tests. Well, you can't have a double blind test. The odor to which I referred is so distinctive that it is impossible to disguise a placebo. One knows instantly whether one is getting the DMSO or the placebo. The doctor has said, figure out a protocol and we will do it.

One foundation, I don't remember the name but it is pretty impressive, laid out a discipline, followed it, and the FDA doesn't like that one now. So it is the difficulty of getting a protocol that will satisfy people who because, as I say, I suspect the broad range of applications, its relative inexpensiveness, I guess, that they just feel suspicious of anything.

Mr. FORD. What happens when they reject one of the applications or will not go along with it? How do they respond, by cutting you completely off?

Mr. DUNCAN. This was done at one time. They did cutoff further experimentation in it. That was back in the sixties. Then they subsequently reinstated it on an experimental basis. If I am not mistaken, experimental protocols can be laid out and would probably be approved by the FDA on an experimental basis. Then gathering the data from all these experiments, hopefully some day the FDA will say, the scales tilt in your favor.

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But they must get over the hurdle of it being safe. It is safe. The only physical side effects I recall was in the early days some massive doses had some reversible changes in the retina of the eye of a rodent. That has never been duplicated in a human being.

Sometimes if you get a high concentration and your skin is tender, you will get a little smarting like you did with Sloan's liniment. But you can get away from that by diluting it in water. The smell, they have not done much about the smell.

Mr. FORD. You have not used DMSO for arthritis, is that correct?

Mr. DUNCAN. No. But I have used it for bursitis and its response of burns. Then I called Dr. Jacob. I was so much in pain, I got the DMSO and put it on and called the doctor and said, hey, I have discovered something, I am way ahead of you. But I was not. Every time I see or I hear of some additional beneficial use of this I call him and he is way ahead of me.

Mr. FORD. Thank you very much, Mr. Chairman.

The CHAIRMAN. Thank you.

Ms. Oakar, would you also like to make a statement?

Ms. OAKAR. Mr. Chairman, I have a statement I would like to submit for the record.

The CHAIRMAN. Without objection it will be received.

[The prepared statement follows:]

PREPARED STATEMENT OF REPRESENTATIVE MARY ROSE OAKAR

Mr. Chairman and Members of the Select Committee on Aging, I would like to thank you for holding this hearing and for the opportunity to speak to you today about this controversial drug, dimethyl sulfoxide (DMSO).

In Ohio alone, over 300,000 people suffer from rheumatoid arthritis. This crippling disease particularly affects women and the elderly, and can be painful, debilitating and costly. The annual cost to the State of Ohio from arthritic diseases is approximately 450 million dollars, not including 175 million dollars in lost wages. Furthermore, in Northeastern Ohio there is a ratio of one physician certified as a Rheumatologist to every 200,000 people. When approximately one out of every seven people nationally is affected by some form of arthritic disease, it becomes readily apparent why these people are so very vulnerable to sales of products and services which promise to ease their pains.

It was reported last year in Medical World News (March 5, 1979) that at least seven clinics have opened in Mexico to treat arthritis patients, primarily Americans, with DMSO. There are strong indications of connections between these clinics and those offering laetrile to cancer patients. The connections are partly philosphical and partly economic, but the important point is that if the drug is not effective or safe, thousands of Americans are being needlessly victimized, and if the drug is safe and effective, then we should be making it available here to those whom it can help.

Congressional hearings alone cannot determine the safety or effectiveness of a drug, but we can examine both sides of the DMSO question and consider what action, if any, is warranted by the Congress.

I hope that you will listen to the testimony of these witnesses carefully. Rheumatoid arthritis afflicts 6.5 million Americans, of whom approximately 75 percent are women. At least 66 percent of those afflicted are elderly. This issue is of deep concern to me and the other members of the House Select Committee on Aging. We owe it to our senior citizens to do all that we can to examine and explore means of making their later years as healthy and as safe as possible. Thank you.

Ms. OAKAR. First of all, I want to commend you for having this hearing. I want to congratulate my friend, Congressman Duncan, for being here. He is well known as one of the fairest people and nicest people in Congress, as well as the most knowledgeable.

Bob, I think you are being a little kind with respect to the FDA, if you don't mind my saying so. There are many cases, in my judgment and based on the limited research that we have done

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here, in which FDA was extraordinarily scrupulous when it came to releasing drugs for use by the American people, and not at all cautious in other cases.

We just heard, for example, that they whisked a drug to Yugoslavia for Chairman Tito who is dying, and yet our own people who are dying with the same kind of affliction cannot get this so-called miracle drug.

We know that a Federal jury recently awarded $20,000 in damages to parents of a child born with birth defects caused by bendectin, a drug commonly used for morning sickness during the first 3 months of pregnancy. Medical journals have reported 180 cases of birth defects due to bendectin, and yet this drug has not been questioned at all by the FDA or taken off the market.

We know that even in the case of aspirin, which is frequently prescribed for arthritis and other types of afflictions, can be damaging. I want to ask some questions when we get to some of the doctors, about aspirin and other drugs and also whether they are being unmercifully scrupulous to a point of absurdity when it comes to DMSO.

While I will accept, as a Member of Congress, some of the responsibility for some of their scrupulosity, I will not accept all of it because I think that they have hindered progress in many areas.

Mr. DUNCAN. Well, Ms. Oakar, the only comment I would make on that, I guess, is that the FDA is not perfect. It is a human institution and subject to the same imperfections as this human institution called the Congress.

While I agree and would be as critical as you in those instances that you have mentioned, I would also say that the American people were pretty grateful to them with respect to thalidomide.

So as far as FDA is concerned, I am asking for an understanding of the difficult, narrow, perilous line that they have to walk. I caution you as you approach the FDA law to understand that the sword that we fashioned to solve today's problem will be used against you tomorrow to deter you from solving tomorrow's problem unless you fashion that sword, that legislative sword, with a great deal of wisdom today.

I guess what I am suggesting is that yes, we need to prod the FDA with respect to their attitudes toward both keeping unsafe drugs off and letting safe drugs on. We also need to look at our own procedures and attempt to anticipate to the extent we can and remove these absolute barriers to action that sometimes do exist in a case like this.

Ms. OAKAR. Thank you very much.

The CHAIRMAN. Mr. Duncan, we thank you very much for coming and giving your valuable testimony.

Mr. DUNCAN. Thank you, Senator. I am grateful to you for holding these hearings. You might be interested to know that Mr. Natcher of the Subcommittee on HEW Appropriations plans hearings on this same subject later in the year.

The CHAIRMAN. Our next witness is another of our distinguished colleagues, Hon. Steven Symms of Idaho.

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STATEMENT OF REPRESENTATIVE STEVEN D. SYMMS, A MEMBER OF CONGRESS FROM THE STATE OF IDAHO

Mr. SYMMS. Thank you, Mr. Chairman.

I appreciated the testimony of my colleague, Mr. Duncan. What he is saying is like the bumper sticker that says, "Caution, FDA Can Be Hazardous To Your Health." That is what we would like to avoid.

I think, as he mentioned, that many of us are grateful to FDA for the work they did to stop thalidomide from being sold in the United States. On the other hand, the nature of the bureaucracy, and this is not limited just to FDA, is that it is much easier and safer for the person who is sitting in the role of the bureaucrat to say no rather than say yes because when they say yes, they do have to take some risks. When they say no, then they are not taking any risks and there are no responsibilities or disruptions that may come. So this is what we are dealing with.

I would just say, Mr. Chairman, to you and members of the committee, I consider it a privilege to be here today and to testify on the innovation and availability of DMSO in the United States and, furthermore, I again would like to commend you for having these hearings so that maybe we can get this important subject off dead center.

As you on the committee know, I have introduced three bills in the House in conjunction with Congressman Bob Duncan which would approve the usage of DMSO for treatment of scleroderma, for the treatment of arthritis, bursitis, rheumatism and other disorders of the muscular-skeletal system, and approve the intravenous use of DMSO for the treatment of acute brain and spinal cord injuries.

Normally, I do not like to introduce legislation for the approval of specific drugs because I believe that the entire process by which the Food and Drug Administration approves drugs for use in the United States should be revamped, and in this regard I have a major reform bill pending in the House, the Food and Drug Reform Act of 1979, which is commonly called H.R. 54 dealing with a broad range of the problems, some of which have already been discussed this morning, the efficacy question, the patent question, and some of the things I think would help move ahead our protection and our safety but also expedite the use of vital pharmaceutical drugs that we need.

I think that I have said many times that there is nothing more ineffective than a product that is unavailable to the public. I think that that is where we have been too carried away with our entire attitude toward efficacy.

However, Mr. Chairman, because DMSO can provide widespread relief for those suffering from muscular-skeletal disorders such as arthritis; provide treatment to those suffering from scleroderma, a disabling disorder in which the skin becomes tight, interfering with blood supply and joint movement; and oftentimes save the lives of those patients who are suffering from injuries or hemorrhaging within the brain because of the ability to reduce intracranial pressure, I believed that specific legislation was urgently needed to make DMSO available for prescriptive use in the United States.

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Despite a myriad of tests and a multitude of patients testifying to the safety and efficacy of DMSO, the Food and Drug Administration still enforces its go-slow edict on DMSO. As a result of the time and money that it would take to encourage FDA to get this compound onto the market, many researchers and pharmacological companies have backed off in their studies.

There is very little that can be said in a complimentary vein for the FDA for it has been a tremendous obstacle to the progress of medicine. The FDA has been solely responsible for driving modern medical research out of this country to foreign soil. Unfortunately, the attitude that more regulations and prohibitions will insure the safety of the citizens of the United States is totally distorted. The fact of the matter is that FDA constraints have caused undue suffering and the loss of life and limb to many of the citizens here in the United States.

It is my hope that by this committee holding these hearings on DMSO, the Food and Drug Administration will not only release this drug for prescriptive use more quickly, but will also realize that the Congress and the citizenry are calling for substantial reform of the drug approval procedure.

I want to thank you again for the opportunity to make my views known on DMSO and the need for drug reform.

The CHAIRMAN. Thank you very much, Mr. Symms. I am glad to know that you have introduced legislation proposing to reexamine the drug approval process now used by the Food and Drug Administration. I don't know whether they are doing the best possible job or not, but it is worth looking into.

This topic must be a part of the subject of our inquiry here today. It has been charged that there is a tremendous drug lag in America. It is also said drugs like DMSO which are not thought to be patentable do not receive proper attention from drug companies who refuse to push tests to get a drug approved with the promise of financial rewards which come from the exclusive right of sale.

The people are entitled to the quickest and ablest determination that can be made as to whether various agents which are proposed to alleviate human illness and suffering are safe for the public use. I commend you on the initiative in causing an inquiry to be made into that matter. Thank you very much.

Mr. Lloyd?

Mr. LLOYD. Thank you very much, Mr. Chairman.

Again, I would like to thank my colleague for being here today. I think you put your finger on it, and I also think my colleague, Ms. Oakar, pointed something out to Mr. Duncan and indeed I agree with Bob that we have to go slowly.

But I also think sometimes we find our governmental agencies really hamper what it is we are trying to do. Am I being unfair in that? What is your comment on that, Mr. Symms?

Mr. SYMMS. I think the gentleman is right on target. It is a matter, again, that I think we have to recognize the nature of how the bureaucratic structure does work and where the incentives lie for those people working within the system. It is not that the people at FDA are not good, sincere people and that they try to do an excellent job. The nature of the bureaucracy is that if you do take a chance and say, approve DMSO, and you are the person who

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signs the order and something turns out bad, then they come back and blame you.

But it is easy if you just say no. You are not faced with the personal crisis that the patient and the doctor are faced with that are trying to get the medicine.

So the physician and the patient in a relationship between those two and the scientific community may be willing to take the risk because if a patient is immobile and unable to live any kind of a normal life, they may be willing to take a risk and try a new product. Yet the bureaucracy itself is insensitive insofar as they are not making a decision based on a personal risk.

Mr. LLOYD. Maybe we ought to consider some legislation—I really feel that perhaps it would be up to you or Mr. Duncan or maybe the chairman of the committee—legislation which in essence says, that the sufferer of this disease, in this case arthritis, although it could be cancer or something else, may request, when witnessed and noted properly, any specific medicine that they feel would be of benefit to them after it is clearly shown by their medical history that they have received the attention of what is known as the normal world of medicine. Then beyond that, maybe they should have that right to use whatever that drug may be. Of course, we have seen this with cancer and in other areas.

They, of course, then assume full responsibility and at that point it relieves the FDA of that responsibility. What would you think of that kind of legislation?

Mr. SYMMS. I think that the problem with that is that most certainly I think in some cases that does happen, even today under our present circumstances. However, if we can't get a policy that can work kind of across the board, which I think my Drug Reform Act would do, to help expedite and get decisions, yes or no—and also our bill goes into the patent problem so that you extend the years of the patent from the time the application is made until it is granted so there is an incentive for people to do it—if you do what the gentleman is suggesting, I think the only weakness, and I would favor that over nothing, is that oftentimes just because of the difficulties of knowledge, distance, communication, et cetera, people may just not know about it. Maybe they have not had the opportunity, say, that Mr. Duncan has had to know Dr. Jacob and know what he is doing with DMSO.

I think what we really need is a broad attitude which would not only cover DMSO but would cover other products. We have had the problem with valferrate. We have had the problem with erythrocin for tuberculosis which took so long to get them on the market in the United States where other places in the world people were using these products very well.

Part of this is because of our overrestrictive amendments which passed in 1962. They have most certainly delineated a cause for a slowdown in the ability of the FDA to make those judgments and make them expeditiously.

Mr. LLOYD. I am trying to address what Mr. Duncan was talking about, which is to be very careful.

Mr. SYMMS. You are saying, allow the patient and the doctor to make the decision instead of the bureaucrat?

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Mr. LLOYD. Only after it has been shown that other methodology has been used. Let me address the one caveat that you had which is that the patient may not know what is in the marketplace.

I am certainly not a medical man but I have found that if there is indeed a methodology, a drug, et cetera, that will address the illness of an individual, particularly if it is available somewhere else in the world, then it is almost universally known to those who suffer from that kind of a physical problem because of the grapevine that occurs. If we know of something that is a good way to work, then we tend to pass that on, particularly in the areas of certain specific diseases, whether it is cancer or arthritis.

For instance, I have found out that I am nearly a medical expert on knee injuries because I have injured my knee so often playing ball. It is not that I am capable of giving medical advice, but in reality I have given advice to people, particularly as to having a knee operation where they remove the meniscus.

I have advised people, particularly if they are still ambulatory, not to make that kind of a decision, without at least doing this, this, this or that. All of this ends up by having them go back to their doctor. But the fact remains that I clearly know the problems that are present.

I am just using myself as an example where I have gone to the library and read a great deal about the subject and made the decisions. I have had what they call orthoscopy done on my knees on three separate occasions. Each time the man says, you should have your knees operated on, and each time I have decided against it.

So I am saying the sufferer has a better feel for the disease sometimes than even medical people, particularly in bureaucratic application where we are trying to take the common denominator. That is what I am trying to address. This is just a thought.

I thank you very much. I have taken much too much time.

Mr. SYMMS. Mr. Chairman, if I can just make one other comment. The overall question of what has happened to the FDA since 1962, if one will study it, and I have spent a great deal of time looking into it, we have a general drug lag, a slowdown because of the efficacy requirements of being able to prove that something is effective.

Now, Bob Duncan just testified that he knows that using DMSO on his shoulder that has bursitis is effective. It may be more difficult or expensive for the pharmaceutical company to prove that, but because of that we have a tremendous drug lag in the United States.

Here is a country that has put 12 men on the moon and yet our patients in this country are not able to have access unless they happen to be wealthy enough to fly to Europe for treatment. They don't have access to products that would be relatively rather inexpensive and we have the wherewithal, the system, the pharmaceutical companies, the technology, the doctors, et cetera, to get these products to the people and the patient.

Yet it is a bureaucratic entanglement in Washington, D.C., which is causing a drug lag. It costs us 50 to 75 cents to $1 for every prescription to prove all these things. There is a slowdown. It becomes a nightmare when one examines what is happening.

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I thank you, Mr. Chairman, again for calling attention to this. Anything any of the members of the committee can do to help me pressure the Commerce Committee to move forward with some real drug reform I think would be very helpful to the patients and the citizens of this country in all due respect to humanity.

The CHAIRMAN. Thank you, Mr. Symms. We commend you, as I said before, for your pioneering in this very critical area.

Mr. Ford?

Mr. FORD. No questions, Mr. Chairman.

The CHAIRMAN. Mr. Hopkins?

Mr. HOPKINS. Thank you, Mr. Chairman.

I want to join my colleagues on this committee in thanking Congressman Symms for being here. For those of you who might not know, he is one of the most outstanding members of this Congress.

What we are really talking about I think is how safe is safe. Certainly I think we all realize the fact that we have to have some regulation in this country. Certainly the FDA does some good. The fact is that the time involved for new drug approval has risen from 2½ years to 10 years. In 1958, one new drug needed 430 pages of submissions. But in 1968, a new anesthetic required documentation totaling more than 72,000 pages and 176 volumes.

Certainly we need some regulation in this country, but I have come personally to the conclusion that Government regulations are excessive.

Congressman, I compliment you on the three bills that you have introduced pertaining to DMSO. Are you optimistic, Steve, about the enactment of these bills?

Mr. SYMMS. Not necessarily optimistic because I believe that the FDA has the ability to prove DMSO without legislation by Congress. As the gentlemen mentioned, how safe is safe? The FDA properly stopped thalidomide from being used in the United States, from being prescribed and put on the market, without the amendments. That was pre-1962. But in the hysteria of the thalidomide scare, and some of it was brought into this country from other countries, the Congress in 1962 passed the amendments.

If you will note the dates of the figures that you gave in 1958 and 1968, the big increase has been in trying to prove that something is efficacious. Safety is another matter. I think we all agree we should try to prove safety. But the small entrepreneur drug company is falling through the cracks because they cannot afford to do a $20 million proving ground to prove that a product is efficacious.

The inexpensive, nonprofitable or less profitable drugs are not as attractive now to the market. The result is that the big companies get bigger and the small companies have a harder and harder time competing in the marketplace.

So I am not so optimistic about our bill passing. I am pessimistic about my Drug Reform Act passing because this is the third Congress in which I have introduced this bill and we have not yet been able to move it out of the subcommittee.

I would hope maybe in the future, with committees like this one becoming more aware of the problem of what the amendments have done, coupled with patent laws and other areas, that we can, in Congress, move forward with a broad-based reform which would

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be better than specific legislation on one product at a time because it puts Congress in a position of starting to vote on individual products.

I am not sure that we in the Congress—we have 2 physicians out of a body of 435, or 3 physicians—that we really have the technical training to start passing judgment on individual drug products. I don't want to get us in that position.

But my motivation to be here this morning is to focus attention on it, hoping that the FDA after realizing that Congress is interested in it, might go back and reevaluate their position and say, why don't we take a chance and list DMSO on prescription only. This means that you will have a physician who is trained in making the judgments making the determination. You are not going to have it sold in the drugstore where we people can use it like horse liniment.

So I don't think that the passage or failure of the bill is what is important. What is important is will the American people who suffer from arthritis, bursitis, scleroderma and other problems have access to any kind of new technology introduced in the United States without having to go through a lot of redtape and hassle.

Mr. HOPKINS. Is your legislation receiving any support from the medical profession?

Mr. SYMMS. There is some interest and encouragement in it, but I think at the most you will have some witnesses this morning who I think can probably answer that better. Most people who are professionals in the medical health dispensary business, so to speak, would prefer to have a pattern where you could have a professional medical board make a judgment on something.

I believe that there should be a time limit within 180 days, and it is in my general reform bill, that the FDA has to say yes or no. So then you know where you are from the private side of the thing so that you can decide, shall we move forward with this product or shall we stop? If you get a flat no after 180 days, you say, let's not spend $15 million here, but let's start on this product.

What is happening is a nightmare, and it is really outrageous. Like I said earlier, the most ineffective drug that there is is the one that you need as a patient and your physician would like to have to treat you and it is unavailable and you have to fly to Western Europe to get it. I think that is the problem.

Mr. HOPKINS. Thank you.

The CHAIRMAN. Ms. Oakar?

Ms. OAKAR. Just one quick question for the Congressman. A yes or no would be fine. I am glad you are here.

Have you used this drug?

Mr. SYMMS. No, I have not. I have had just a slight bit of experience with DMSO insofar as with my wife when I have rubbed some on her and you can taste it instantly. But I have not had any problems.

Ms. OAKAR. Did it help your wife?

Mr. SYMMS. Not particularly. In her particular instance it did not. But I don't think she gave it a fair test. But I think the patients have to make these decisions. Her choice has been not to go that course of treatment.

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Ms. OAKAR. Thank you very much.

The CHAIRMAN. Thank you, Mr. Symms. We appreciate your being here.

Now we will hear Dr. Stanley Jacob. Would you please come to the table?

Dr. Stanley Jacob is associate professor of surgery, University of Oregon Medical School. Dr. Jacob is a graduate of the Harvard University Medical School and has been recipient of the Markle Scholarship in Medical Sciences, the Kemper Foundation Research Scholarship of the American College of Surgeons, and the First Place Glycerine Research Award.

Dr. Jacob has published over 40 papers in scientific journals on such research as overcoming surgical shock, prophylactic use of antibiotics, and restoring blood production in leukemic children. His research on the clinical use of DMSO dates back to 1961.

Dr. Jacob, we commend you for your initiative in trying to meet the challenge of suffering and pain experienced by so many millions of your fellow citizens. We thank you very much for coming here today to tell us about this drug that you have initiated and which you have recommended.

STATEMENT OF DR. STANLEY JACOB, ASSOCIATE PROFESSOR OF SURGERY, UNIVERSITY OF OREGON MEDICAL SCHOOL

Dr. JACOB. Thank you very much, Mr. Chairman.

Mr. Chairman and ladies and gentlemen, I brought a bottle of DMSO with me. This is in 70 percent concentration. It looks very much like water. In the United States it is made from the cement substance of trees, lignin. It can be made from any inorganic base such as coal or petroleum very inexpensively produced. It is a very simple chemical.

In my opinion, in our century we have had three truly significant therapeutic principles. These are: Penicillin of 1927–28, cortisone of 1948, and DMSO of 1963.

Now the difference between a therapeutic principle and a drug is that a drug is useful in treating a disease or a dozen diseases or even 100 diseases. But a therapeutic principle is an entire new means of treating illness.

The basic therapeutic principle of DMSO is that one can treat disease by altering what normally goes into and comes out from cells. Because we are not dealing with a drug in the conventional sense, this is one of the reasons that DMSO is not available today.

The people at the FDA, unfortunately, do not understand this concept. I fear that if the situation continues the way it is with people in charge at the FDA and the current division in charge of it, with this group not really understanding this compound, we will not see DMSO available for a fraction of its potential within this century.

Now we began working with DMSO in 1962. In 1965, three American pharmaceutical firms, Merck, Syntex, and Gibb, submitted new drug applications to the FDA stating that DMSO was ready to be a prescriptive agent. These three were turned down.

In 1971, Gibb submitted another NDA stating that DMSO was ready to be prescriptive in the United States. This was turned down.

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Most recently, Research Industries Corp. submitted to the FDA a NDA stating that DMSO was ready to be prescriptive for scleroderma. This was turned down.

I do not believe there is another substance which has been turned down five separate times, five NDA's by the FDA. One of the major points brought up by the FDA is that DMSO, that the studies are not well controlled.

I have in front of me the Washington Post, April 24, 1968. It is entitled "FDA Approval of Drug Hit." This talks about a drug called Indocin which the FDA approved at the same time they not only stopped testing on DMSO in 1965 but actually turned down three NDA's.

The approval of Indocin was investigated by a congressional committee. The conclusion was that there were 137 studies submitted on Indocin to the FDA. Only three of these studies were considered to be well controlled and those three were subsequently shown to have been biased.

So what we have here is a situation where the FDA approved an agent which happens to be expensive which is used for the treatment of arthritis with, in essence, no controlled studies, at the same time they turned down DMSO.

Now at that time when Merck, Syntex, and Gibb submitted NDA's to the FDA, there were between 1,300 and 1,500 studies committed on 100,000 patients. These were all tossed aside. These were all turned down. The FDA approved Indocin and a congressional investigation subsequently showed that the studies on which Indocin approval was based were certainly not controlled.

It is difficult not to become emotionally involved with DMSO. The reason it is difficult not to become emotionally involved is that over the last 18 years we have literally treated thousands of people. We have visited every country in the world where DMSO is prescriptive. We have read every publication in the literature relating to DMSO that we could find. We have written several books on DMSO. I brought them here.

Interestingly enough, this book which is entitled, "Dimethyl Sulfoxide," doesn't come from the University of Oregon Medical School. It comes from behind the Iron Curtain. It contains 3,500 references. Not all of them are on the medical uses of DMSO.

But we are not talking here about a substance that is not well steeped with scientific background. We are talking about an agent which has been studied in just about every medical school in the world. There are literally thousands of scientific articles. I think it can be stated without qualification that this is safe and effective for many diseases for which we do not have other treatments and for many diseases for which we do have other treatments.

Before coming here, I picked up a book in the newsstand entitled "Montgomery Clift." On page 392 there is a paragraph which starts: "Bachrach began by giving him injections of aristocort, that is, cortisone in his shoulder. This worked well, gave him relief, but it was too strong. It ultimately would have disintegrated the shoulder bone.

"Later he suggested Monty try DMSO which was a great new painkiller. You just rub it into your skin like a lotion. It comes out of your lungs and skin and smells like horse, you know what. But

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the stuff was miraculous. For the first time in years Monty was completely without pain. He stopped taking Demerol.

"I invited Bachrach out to the house for dinner. Monty was able to use DMSO for several months before the FDA took the drug off the market labeling it unsafe. DMSO had been tested on rats eyes and the female rats got pregnant. The males developed cataracts. Monty was furious.

"Bachrach told him, look, they are not sure what the side effects of this drug are on humans, to which Monty retorted, 'I have had cataracts and I can't get pregnant, so what the heck.'

"Monty wanted the DMSO so much that he managed to get it through a vet. When he was unable to attain it any more he went back on Demerol." As many of you know, he eventually died from an overdose of narcotics.

I know this committee is most interested in DMSO in arthritis. Based on 18 years of experience, based on treating arthritic patients resistant to no other modality of treatment, I am willing to go on the record that there is no question that this agent is safe and effective for arthritis, at least in relieving pain.

Now this can be shown by article after article in the scientific literature. The Germans have studied 10,000 patients using historic controls with 70 to 80 percent rate in degenerative arthritis, rheumatoid and gouty arthritis. Gibb has an article in this particular book on 2,000 patients, many of whom have arthritis, most of whom were resistant to other modalities of treatment, again with .

People say to me, why did I finally decide to speak out on this issue after remaining quiet for 6 years? There were two reasons. One was that we submitted data on a disease called scleroderma. It is a horrible disease that affects maybe 50,000 to 75,000 people in the United States. The skin becomes taut, the blood vessels have diminished blood supply to the extremities. Patients develop painful ulcers. If these ulcers do not heal, amputation of the fingers is necessary.

We went to the FDA in 1974. We designed a protocol to study DMSO in scleroderma. We followed that protocol. We submitted data in 1979, an NDA which was heard by the FDA, and it was turned down. Now, scleroderma is an orphan disease which affects a few thousand people in this country. The DMSO was used in patients who had ulcers which were resistant to all other modalities of treatment. Dr. Arthur Scherbel, who is one of the world's leading experts on scleroderma, will speak to this point today.

The alternative to DMSO for these patients is amputation. Yet the FDA turned down this application. This to me is unconscionable.

The second reason I decided to speak and to bring this case to the American people is that we now have solid animal data from the University of Chicago, and Dr. Jack de la Torre who did the work is here. Jack is currently chairman, or in charge, of neurosurgical research at the University of Miami.

At the University of Chicago they have done extraordinarily precise evaluations in monkeys, dogs, and other animals showing that DMSO is clearly the treatment of choice when it is given intravenously to animals with what ordinarily would be lethal stroke, lethal head injury, and lethal spinal cord injury.

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At our medical school in October of this year we presented data on 11 patients with severe head injuries. These were people who had markedly elevated pressure in the brain, secondary to head injury. Six of the eleven patients were resistant to other modalities of treatment, of great historic control.

Despite the fact that they are resistant to barbiturates and mannitol which are the treatments currently used, they were all given DMSO and within 3 to 5 minutes the pressure came down to normal. We have another five patients in whom we started DMSO as the initial treatment of choice in which the results in terms of survival were much better than when we waited until the end.

But I came here today and I agreed to go on "60 Minutes" and I want to bring this case to the American people because we have to select between a bureaucratic way of life and people losing their fingers or losing their lives. This is a serious question. It is not a game. Yet a game is being played. I would like to try to answer any questions that anyone would care to ask of me.

The CHAIRMAN. I would suggest to the committee that we hear the other doctors and then we can question all of them.

Dr. JACOB. Thank you very much.

[The prepared statement of Dr. Stanley W. Jacob follows:]

PREPARED STATEMENT OF DR. STANLEY W. JACOB

The passage of the Kefauver-Harris amendments in 1962 has been followed by an obvious drug lag in the United States. By "drug lag" I mean:

1. Reduced rate of discovery and development of new therapeutic entities.
2. Increased period of time to move new drug discoveries from the laboratory to prescriptive use.
3. Restricted release of new drug entities in the United States compared with other technically advanced countries.

Since 1962, the United States Food and Drug Administration has grown in both power and population—in many ways like a malignant tumor. There are at least four serious side effects secondary to the way the FDA has functioned:

1. FDA regulations have increased the cost for therapeutic substances.
2. FDA regulations have brought about a termination of research on many therapeutants which might be useful in so-called "orphan" diseases, that is, diseases affecting fewer than 100,000 Americans.
3. FDA regulations have brought about a de-emphasis of research and development of the so-called "soft" (less toxic) drugs which are difficult or impossible to clear through the present methodology of required by the FDA. If aspirin were to be introduced today, it would fall into the category of a "soft" agent of low toxicity.
4. The FDA has brought about a de-emphasis of research and development on drug combinations.

I would like to discuss dimethyl sulfoxide (DMSO).

My major research interest since 1962 has been the pharmacology and clinical usefulness of DMSO.

Dimethyl sulfoxide in the United States is derived from lignin, the cement substance of trees. It can, however, be made from a number of organic chemicals and may be inexpensively produced.

DMSO was first chemically prepared in 1866 but remained a laboratory curiosity for more than three quarters of a century. In 1948, a number of papers began to appear in the chemical literature showing it was a solvent for many other substances. In 1959, a group in Great Britain demonstrated that dimethyl sulfoxide would protect red blood cells and other tissues against freezing damage.

The use of DMSO as a drug was not shown until a collaborate effort between scientists at the University of Oregon Medical School and the Crown Zellerbach Corp. demonstrated in laboratory tests that DMSO would not only pass through the skin and mucous membranes, but during passage would carry with it a certain number of other substances. For instance, Penicillin can be dissolved in DMSO and be carried through the skin without a needle.

In these early studies, dimethyl sulfoxide was shown to relieve pain, reduce swelling, slow the growth of bacteria, improve blood supply, soften scar tissue,

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enhance the effectiveness of other pharmacologic agents, serve as a diuretic, and act as a muscle relaxant.

The first report on the use of dimethyl sulfoxide as a pharmacologic agent was written in 1963 and published February 1, 1964. The first IND to study DMSO clinically in the United States was submitted on October 25, 1963. Three NDA's on DMSO were submitted to the FDA in 1965. All were turned down. A fourth NDA was submitted in 1970. It was also turned down by the FDA.

Yet, the New York Times in a lead editorial on April 3, 1965, called DMSO "the closest thing to a wonder drug produced in the 1960's."

Several thousand scientific articles on DMSO have appeared in the world's literature. In our reference library at the University of Oregon Health Sciences Center, we have a fairly complete bibliography which includes seven technical books on dimethyl sulfoxide.

Four international symposia have been held on DMSO. The first of these was in Berlin, Germany, in July, 1965. The second was under the auspices of the New York Academy of Sciences in March of 1966, New York City, New York. The third was sponsored by the University of Vienna, in Austria, November, 1966. The fourth was again in New York, under the sponsorship of the New York Academy of Sciences in January, 1974.

Of major importance is the fact that DMSO has been shown to be of value, not only in diseases for which there is other known treatment, but in a number of illnesses for which no other effective or low risk treatment is known, such as the painful ulcers of the fingers in patients with scleroderma. In this disease the skin becomes tight and the joints are prevented from moving. Microscopic sections of skin from patients with scleroderma have been studied before and after treatment of DMSO. These studies demonstrated definite improvement with DMSO therapy—without DMSO, some of these patients would require amputations.

The value of DMSO in other illnesses for which effective pharmacologic treatment does not presently exist, includes severe abacterial prostatitis, Dupuytren's contracture, subcutaneous scarring from cobalt irradiation, keloids, Peyronie's disease and potentially in otherwise "irreversible" injury to the brain and spinal cord.

A broader spectrum of primary pharmacology and potential benefit, both actual and potential, has been described in the scientific literature for DMSO than for any other substance with which I am familiar. No attempt will be made at this point to record the long list of entities for which benefit from DMSO has already been responsibly reported in the literature. In my opinion, DMSO is the treatment of choice for severe acute musculoskeletal trauma (such as strains and sprains) and acute and chronic bursitis.

Dimethyl sulfoxide is a useful adjunct in the treatment of rheumatoid arthritis, degenerative arthritis and gouty arthritis. It primarily will relieve pain, but will also reduce inflammation and increase joint mobility. Due to its effectiveness in the treatment of arthritis, Americans by the thousands are flocking to nations such as Mexico to receive DMSO. In Mexico they are charged seven to eight hundred dollars for three days of treatment. One entrepreneur in this "South of the Border" country presumably treated with DMSO thirty-thousand Americans last year for arthritis and grossed over twenty million dollars.

The effectiveness of DMSO has been demonstrated by comparative studies, by "double blind" studies, and by the clinical impression type of evaluations in man.

Dr. J. Harold Brown, formerly President of the Aerospace Medical Association, included in his "double blind" report the following statement:

"I am convinced that topical application of DMSO in the treatment of acute musculoskeletal conditions is a striking and significant therapeutic contribution. During the period of time I conducted clinical investigation with this medication, I practically discarded physical therapy as treatment for musculoskeletal problems because the rehabilitation of my patients was so prompt with DMSO. There was little or no necessity to prescribe narcotics and tranquilizers since pain was promptly mitigated following topical application of DMSO."

The further usefulness of DMSO has been shown by the fact that it is now prescriptive in the United States for acute musculoskeletal problems in small and large animals, approved by the Veterinary Division of the Food and Drug Administration in 1970.

An important question about any drug is toxicity. There is no such thing as a non-toxic drug. DMSO has its side effects. The major side effect of DMSO is the possibility of an occasional patients being hyper-sensitive.

I believe there are more data on animal toxicology regarding DMSO than have ever existed for any other experimental drug. I have not had experience with any drug in medicine which I consider to be safer. In my estimation there are more data on human toxicology of DMSO than have ever been obtained for any other experi-

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mental drug. The Food and Drug Administration itself has data on over one hundred thousand patients. Despite the prescriptive use of DMSO worldwide, there is, to my knowledge, not a single case of well-documented serious toxicity.

Dimethyl sulfoxide is currently a prescriptive agent in the United States for interstitial cystitis. It is prescriptive in Canada for scleroderma. It is prescriptive in Great Britain and Ireland for shingles when mixed with IDU. It is prescriptive for a whole range of disorders for topical administration in Germany, Austria, and Switzerland. It is widely prescriptive in many parts of South America. It is prescriptive in the Soviet Union and has been since 1971.

When Dr. Chauncy Leake, one of the world's most eminent pharmacologists, reviewed the New York Academy of Sciences Symposium on DMSO in 1966, he stated that the well known legal phrase "res ipsa loquitur" applied to the DMSO situation. In summarizing the conference, Dr. Leake said,

"Rarely has a new drug come to the attention of the scientific community with so much verifiable information, from so many parts of the world, both as to safety and effectiveness."

There is little doubt but that DMSO should be prescriptive in the United States today for a whole host of disorders, including its potential for pain relief in arthritis. It is prescriptive only for one numerically insignificant entity, interstitial cystitis.

I am willing to make the statement to this Committee that there is no question concerning the effectiveness of DMSO. It is one of the few agents in which effectiveness can be demonstrated before the eyes of the observers. For instance, if we have patients appear before the Committee with edematous sprained ankles, the application of DMSO would be followed by objective diminution of swelling within an hour. No other therapeutic modality will do this!

If we have patients appear with acute bursitis unable to move a shoulder in any direction, the topical application of DMSO would be followed by a dramatic increase in the range of motion at the end of a half hour. If we had patients appear with chronic bursitis, the topical application of DMSO would be followed by a notable increase in the range of motion within a half hour.

If we had patients appear with fresh ecchymoses such as an early black eye, a topical application of DMSO would be followed by a reduction in this discoloration within one hour.

An NDA on DMSO for scleroderma was submitted almost three years ago. During this time we have revised the submission several times to meet decision delaying tactics. FDA is currently considering whether to require additional months, or most probably years, before they approve this indication. These delays cause unnecessary suffering for thousands of Americans and possibly the loss by otherwise unnecessary amputation of fingers, toes, and limbs. This is an intolerable situation.

Dimethyl sulfoxide (DMSO) is a particularly promising treatment with injuries of the central nervous system (brain and spinal cord). Data from lower animals and man indicate that DMSO may be more important than any other pharmacologic agent in treating injuries to the brain and spinal cord.

With such a promising new medical application for DMSO, one might presume that we are satisfied and optimistic about the project's future. This is far from the truth. Results with CNS accidents, to date, though dramatic and life-saving, are not even fractionally different from multiple clinical findings with DMSO for other disorders.

Heretofore, every time we have concluded a clinical study demonstrating and safety with DMSO, we have been rewarded with a new stabilized, FDA position of confoundment. An obdurant barrier of bureaucrats housed in the office of the FDA has shredded the data with their own, unique methodology. In their house, supported by public funds, they play dangerous games—harmful games with truth, statistics, objectivity, ethics and the health and welfare of citizens of the U.S. If their policies with DMSO are an accurate barometer of their general procedures with food and drug policies, the Bureau, itself, may be a great hazard to the health of the people of this country.

Let me make a grim prediction concerning the fate of our CNS–DMSO projects. Unless responsibility for DMSO decisions are removed from the FDA or the FDA is subject to a radical change in management, despite the potential saving of tens of thousands of lives per year or prevention of permanent paralysis, post-CNS accident, FDA will continue to block public access to the drug for at least several years. Recall the so-called "historical" control to this matter—FDA has blocked other important medical usage of DMSO in man for more than a decade.

The major question continues to be, has the public benefited, or has the public been harmed by the FDA blockade on approving DMSO. If DMSO had been truly a nostrum, or even worse, a drug associated with serious clinical toxicity, the public would have benefited by FDA actions. If, as overwhelming scientific evidence indi-

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cates, DMSO is a significant medical advance with minimal clinical toxicity, then the public has been and continues to be harmed by the FDA approach.

The CHAIRMAN. Next will be Dr. Arthur Scherbel.

Doctor, will you give us a bit of your background?

STATEMENT OF DR. ARTHUR SCHERBEL, CHIEF OF RHEUMATOLOGY, CLEVELAND CLINIC FOUNDATION

Dr. SCHERBEL. Mr. Chairman, I apologize for not having a formal presentation to give to you today.

The CHAIRMAN. That is all right. We are glad to have you give us verbal testimony.

Dr. SCHERBEL. My background is as follows: I am the founder of the Department of Rheumatic Disease at the Cleveland Clinic Foundation. At the present time I am senior consultant in that department. I am the immediate past president of the American Society for Clinical Pharmacology and Therapeutics.

In my specialty I deal with patients who have very serious diseases which indeed are challenging to any form of therapy. For the past 25 years I have been very interested in therapy of the rheumatic connective tissue diseases. To be very frank with you, we do not have good, highly effective therapeutic agents. We have no drug today that is completely and totally effective and without toxicity.

However, we accept all that. Those of us who treat these diseases know how to use these drugs to best advantage and we do it the best we can. We have no silver bullet.

During the past 25 years I have had the opportunity to evaluate numerous drugs. Some have been approved by FDA and others have not. Certain new drugs studied experimentally have been found highly effective, but in clinical practice they are only minimally effective. These drugs are not comparable to the effect of antibiotics in infectious diseases.

I began to use DMSO approximately 15 years ago. Initially I was also skeptical about the drug. It is a solvent that has been used commercially and in laboratories. Dr. Jacob was the first to discover that this drug was rapidly absorbed through the skin, relieved pain, and in some instances it relieved swelling and inflammation.

He asked me if I would study the drug. There is no doubt in my mind, the drug relieves certain types of pain. It is not a curative agent and all the reports we have read about "miraculous and outstanding" should be completely disregarded. There is nothing miraculous about this compound at all, but it does relieve pain in a temporary manner. It is not a cure. None of our antirheumative drugs are curative. DMSO applied topically is indeed a safe, therapeutic agent to use.

There are, as you know, many people with many forms of so-called rheumatism or arthritis who abuse aspirin, who abuse propoxyphene, codine, oxycodone, and many other drugs that relieve pain. Many do not tolerate aspirin. It may cause gastric irritation when administered in frequent large doses. If one likes to drink alcohol while taking large doses of aspirin he may end up in a hospital emergency room with severe gastric hemorrhage.

I don't criticize aspirin; it is perhaps the most frequently used drug in the world. Elderly people who use aspirin and have im-

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paired hearing may notice aggravation, or if they have ringing in their ears, it may increase. Aggravation of these symptoms may be permanent.

We don't want elderly persons to become deaf while taking pain-relieving medication. Therefore, we try and find various ways of using a combination of drugs that we have in our therapeutic armamentarium. Certain patients will notice a greater effect from one drug, while other patients will have more effect from another drug. So these are some of the therapeutic problems that we encounter. There is nothing simple in the treatment of the diseases that we are discussing today.

The disease that I would like to talk to you about very briefly is scleroderma. Scleroderma is a very serious disease. It involves many organs of the body. There is an abundance of collagen in many organs of the body. Blood vessels tend to thicken. The inner lining of small blood vessels thickens and the lumen may close. In many of these patients ulcers will occur at the fingertips.

All patients with scleroderma do not have serious disease, but in most people there is slow progression over a period of 10, 15, or 20 years. If fingertip ulcers occur, they are painful, and finger motion is restricted.

The problem that exists when a double blind, controlled study is carried out is the odor that occurs as well as the characteristic effect observed on the skin.

We treated patients with the most severe types of ulcers, ulcers that did not heal, ulcers which lasted a year or longer. One hand was treated and compared with the untreated hand.

The study was planned with doctors at FDA and consultants from the National Academy of Sciences. We carried out these studies and indeed we saw changes in the treated hand, as compared with the untreated hand. In 3 months there was a marked difference which was statistically significant.

But at 6 months the untreated hand was beginning to show improvement. We believe this resulted from DMSO traveling through the blood stream to the untreated hand. We also noticed the same effect with pain relief. If we treated one hand, lo and behold, in 3 weeks there was less pain in the other hand. We believe this is systematic effect of the drug which results from rapid absorption into the tissues.

When we came to FDA with this explanation, this was not statistically significant in their view and therefore they could not accept the study. We showed objectively that there was an increase in grip strength in the treated hand compared to the untreated hand. We noted that ulcers healed more rapidly in the treated hand as compared with the untreated hand. We also noted that there was less frequency of recurrence of ulcers in the treated hand as compared with the untreated hand.

One of the investigators at the New York University found that his pathologist could interpret from histologic sections which patients were treated with DMSO. He did not know if the patient had received treatment or not, but in 8 out of 11 cases he was able to show histologically which patients received treatment.

We believe we have good evidence to show this drug is effective for this condition, but we have not been able to convince FDA that

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these patients have benefited from treatment. I believe, as do these patients, that pain relief and improved ulcer healing occurs with treatment. We have been unable to perform a true double blind study because of the unique characteristics of the drug.

Many of the FDA officials are very good friends of mine. I know them well and I agree that an unbiased study is desirable in the study of any drug. But one cannot take this drug with its characteristic odor and permeability and carry out a true double blind study.

Moreover, many patients in the study were sent to us with severe ulcers. The referring doctors requested DMSO treatment before resorting to amputation of fingers. We could not take these patients and place them in a randomized study.

Ten years ago, we reported on the effect of DMSO on cutaneous ulcers while using the patient as a historical control. We did a second study which was planned with members of FDA. When the study was completed another group of FDA officials was assigned to evaluate the results. The second group turned down the study. I am critical of the double standards imposed on us as a result of a change in FDA monitors while this study was in progress.

If one looks at the objective criteria submitted, it is statistically valid material.

For those patients who could indeed profit from the use of a very simple drug, we cannot use it unless we carry out a very strict protocol. If I wanted to give this drug to a patient today, I must obtain sophisticated eye examinations every 6 months. This patient must have blood studies every 3 months. If this patient lives 150 miles from Cleveland, he or she must come back at a determined time and the studies must be carried out according to FDA regulations.

Long ago we realized that toxicity was not a problem but we do not dare to give this drug without carrying out a battery of very sophisticated laboratory studies. Who pays for this? The patient might not have funds to pay. Will the Cleveland Clinic? They will if I ask them to, but it is not fair to the Cleveland Clinic to do this because it is the FDA request.

If we obtain funds from a pharmaceutical firm and eventually they sense this drug is not going to be approved, where do the funds come from to continue treatment for this group of patients?

Now, in summary I would like to state that we have made no claims for cure with this drug. It affords purely symptomatic relief. It is a palliative drug. It has minimal or no toxicity when used as recommended. It does have an odor. If patients use this drug before going to church, their friends will not sit with them in the same pew, but the odor is a problem that we have to contend with. I don't think this drug will ever be abused. I think people will use it only when they need it and they won't use it when they don't have to.

My recommendation would be that this drug should indeed be made available for the treatment of various forms of arthritis, rheumatism, ulcers in patients with scleroderma. It should also be used in shingles. I have never seen a patient, and we have treated many, who has developed postherpectic neuralgia. It is a very

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disabling type of complication but we don't see it when DMSO is used for treatment of the acute lesions.

So there are many indications where this drug would be of value to the private practitioner as well as to the patient.

Thank you.

[See app. 8, p. 135, letter from Dr. Scherbel, dated March 31, 1980.]

The CHAIRMAN. Thank you very much, Dr. Scherbel. We appreciate your valuable contribution. We will come back to questions in a little bit.

Our next witness will be Dr. Graham Reedy. Dr. Reedy is a fellow in the American Academy of Sports Medicine and a fellow in the Society for Family Medicine. He runs a sports, fitness and family medicine clinic in Enumclaw, Wash. Dr. Reedy began his medical career in the San Francisco Bay area where he became the team physician for the Oakland Raiders in 1971. After 5 years in this position, Dr. Reedy moved to his present home in Enumclaw where he is actively involved in his clinic practice and in community education on preventive health maintenance and drug abuse. Dr. Reedy is a graduate of the University of California Medical School at Irvine. His present primary interests are in sports and fitness medicine as well as family medicine.

Dr. Reedy, we are pleased to have you and will welcome your statement.

Gentlemen, you know we have a number of witnesses here. We don't want to miss anything that is very relevant or important, so please summarize your statements as much as you can.

Thank you, Dr. Reedy.

STATEMENT OF DR. GRAHAM REEDY, FORMER TEAM PHYSICIAN, OAKLAND RAIDERS, ENUMCLAW, WASH.

Dr. REEDY. Thank you, Mr. Chairman and Members of Congress. It is a pleasure to be here and talk in a different vein than has been previously presented relative to the benefits of DMSO and the utilization with soft tissues and swelling due to these particular injuries.

My first experience with DMSO was in 1971. That year I became the team physician for the Oakland Raiders professional football team. My scientific interest in DMSO was initiated while in medical school in 1965. However, shortly thereafter it was removed from the market. I had never used or observed the drug in use until 1971.

Some of our football players were friends of the jockeys at the Golden Gate Race Park near Berkeley and obtained DMSO from them. They had very good success with reducing swelling of acute injury problems prior to my coming to the team. By October 1971, I contacted Dr. Jacob about obtaining some DMSO to use on an experimental basis. I then began to use 70 percent DMSO, as suggested by Dr. Jacob, with careful explanation to each player about its experimental use, such as its side effects of clam breath and skin irritation up to 72 hours past its use. Our application technique was to apply it liberally all over the affected joint or muscle, letting it dry for 5 minutes. This procedure would be repeated up to four times. These treatments occurred from two to

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four times per day for 3 to 4 days. Frequently, players were hospitalized for their severe acute joint or muscle problems. They were immobilized, iced, and elevated for 48-hour periods during which DMSO would be applied in the fashion prescribed. Over a total of 5 years, DMSO was used approximately 20 to 30 times per year. Some of the players who used the drug were Ben Davidson, Tom Keating, Daryle Lamonica, Fred Belitnikoff, Jim Otto, and Bobby Moore. Its greatest value was in its application in the first 3 to 4 days of an acute injury of a muscle or joint having severe swelling. Our experience was significant reduction occurring 70 percent to 80 percent of the time with these injuries. Probably the most dramatic was in a severe elbow contusion to Bobby Moore after a pileup during a football game. During the initial application immediately after the game, actual dimpling was observed as the swelling was reduced. Dr. Robert Rosenfeld, our team orthopedist, again discussed this unusual response as recently as 4 days ago. It was also noted that significant pain reduction was experienced. Therefore, primary benefit to the player was in rapidly diminishing swelling of the muscle or joint and reduction of pain which, after 48 hours, allowed us to hasten our rehabilitation activities. Player's usual estimate of benefit was 50 percent to 75 percent quicker return to playing than from his previous injury experience. Double blind studies were attempted and found to be absolutely of no value due to the specific aspects of the drug. A 10 percent DMSO solution was used but the effect of the placebo was to have much less clam-type breath, only minimal type redness of the area treated, and drying faster than usual in the 70 percent solution.

[See app. 9, p. 136, letter from Daryle Lamonica.]

Dr. REEDY. Just a bit of a vignette. We had a player, Fred Belitnikoff, who had a shoulder contusion and an ankle contusion in a pileup. Seventy percent was applied in the ankle and only 10 percent in the shoulder. He very quickly told me, Doctor, that is not the real stuff, it is not red and it dries too fast. So double blind studies were not able to be completed.

Our experience and usage of DMSO in chronic pain problems or joint disabilities was not especially helpful. However, we may not have given it a good try. We abandoned the use of the drug very soon when we experienced minimal response and had read that it was not as effective in chronic injuries.

This may well have been premature, however, because the drug did not always have a seemingly dramatic response on all people. Some 20 to 30 percent seemed to have only minimal benefit from its use for no explainable reason. This may have been merely an idiosyncrasy to accept or reject the drug. Interestingly, fair-haired and fair-complected players seemed to experience skin reactions sooner than those of darker coloring. It should be stated that the degree of skin reaction was not proportional to the beneficial response of reducing swelling.

In summary, our particular drug indications were for acute swelling due to trauma of any joint or muscle, particularly of the extremities, especially the ankle, elbow, hands, or wrist.

The adverse effects were: One, clam-oyster breath, unresponsive to a myriad number of breath deodorizers. Two, local skin reactions, usually by the 3d to 4th day or by the 9th to 16th treatment

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session, somewhat sooner in fair-complected, light-haired players. These symptoms usually disappear within 72 hours after the last treatment session. I should also state that these effects were welcomed by many of the players to get them back to play sooner.

The benefits: 70 to 80 percent received good to excellent results by reduction of swelling and pain, and consequently, quicker rehabilitation time from that particular injury. These benefits were noticed by the athletes by comparing their own previous injury experience and the experience of others with similar types of injuries.

The conclusion: DMSO, at 70 percent concentration, is an excellent drug which seems to significantly shorten the rehabilitation time for sports injuries to soft tissue or joint defusions. It would definitely make a significant contribution to assist those of us in the field of sports medicine, private practice, and industrial medicine.

It seems to me that one of our major objectives is to get people back to their activities quickly. So the primary significance in the use of DMSO may not be just in the relief of pain but in the ability to rehabilitate that person more quickly. Therefore, it might in essence save us millions of dollars as a nation by rehabilitating the industrial-injured patient and getting them back to work.

I should quickly state that one of our questions is what are the alternatives to this particular method. As was indicated last night on "60 Minutes," one of the treatment courses for bursitis or acute shoulder pain is injections with particular cortisone techniques or cortisone substances. This has now been reputed in much of the medical literature because it is considered to be not effective on an ongoing basis because it may reduce the tensile strength of the muscle or tendon on which it is being injected. So it is not a good alternative.

We are always concerned about invasive versus noninvasive procedures. DMSO fits into the noninvasive character. I would like to see the drug utilized as a second or third course of action after other things had been utilized because it in fact may be the very best initial drug. I would hope that would not be the form of recommendation if in fact cleared to be utilized.

In closing, I would say that we are not interested in just pain relief. In professional football and sports injuries we are interested in rehabilitation time. If in fact we can reduce pain, reduce swelling, and more quickly rehabilitate that player or person back to his activity, we can significantly decrease the loss of playing time, the loss of work time, and increase the quality of life such as in the patients demonstrated last night on "60 Minutes."

Thank you.

The CHAIRMAN. Thank you, Dr. Reedy, for your valuable statement.

We will next hear from Mr. June Jones, quarterback on the Atlanta Falcons professional football team.

STATEMENT OF JUNE JONES III, QUARTERBACK, ATLANTA FALCONS

Mr. JONES. Thank you, Mr. Pepper.

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I guess my function here today is one of not only as an athlete but as a citizen of this country. I very strongly believe in the testimony of Dr. Reedy as far as athletic injuries.

But not only have I had the experience of using this drug with my athletic endeavors, but also I have found, and I have become emotionally involved with the drug also, as Dr. Jacob talked about, basically because I have seen people get amazing results. Most recently I have seen a person who had not walked in close to 6 years. He has not moved his toes in close to 8 years. Just by chance I bumped into this guy and—for the relief of pain he put it on his spinal cord, not thinking it might do anything else—he is walking now within 2 weeks after using it.

That to me is what this thing is all about, not as far as athletes, not as far as anything else, but it is the common person, the citizen of this country, that is suffering and not able, doesn't even know anything about this drug, can't even tell you what DMSO stands for, when I really believe it is probably the most important thing in the medical world.

I am not up-to-date and I don't claim to be a medical genius, but I can tell you this will be the most important thing in my lifetime to come on the market.

Mr. Hopkins, I believe you said earlier that this drug is relatively inexpensive to produce, $4 per quart. I have found in the last 8 to 9 years the process the Food and Drug Administration goes through to legalize this drug, now I am not sure but I am relatively positive that this drug because of all the costly bureaucratic things that you have to go through to get this drug, that now it costs for 4 ounces around $10 to $12. So that is quite a different expense.

I have had an experience that almost ended my football career and without DMSO I would not be playing today. I had a calcification in my right shoulder, my throwing arm. I could not practice some days, could not put on my coat, could not sleep at night. It was threatening to end my career.

When I signed my contract with the Atlanta Falcons I was hoping they were not going to take me out to the football field and watch me throw a ball because I could not throw from here to you. Fortunately I had used DMSO for ankle sprains and contusions in high school but I never thought of using it for my shoulder. So kind of by chance I read in the paper about Dr. Jacob's work and went up to see him. I was treated with DMSO. I used it in my senior year and it got me through the season relatively pain free.

As Dr. Reedy said, athletes don't like to smell like that all the time. I started using it on Thursday and by Saturday I would go 5 or 6 hours pain free. I would go through this for 6 months from July to December. Finally I said, maybe if I just don't do anything with my shoulder anymore, it is going to be all right. So from December until the first part of April I didn't lift a weight, throw a football. But my shoulder got still worse.

I went up to see Dr. Jacob and he gave me an injection in my shoulder. He told me if I used it for 30 days straight, that that calcification would disappear.

To say the least, I went to camp in July, pain free, not using DMSO, and the X-rays showed no calcification in my shoulder. I took cortisone, butazolidin, and all the things the team physicians

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told me would help my shoulder. They did not. The only thing that helped me was DMSO. Without this drug I would not be playing today.

Some of the guys on our team would not step forward to talk about the drug basically because the front office and management frown upon you doing anything they don't want you to do. Any time you mention drugs and the NFL, immediately—in fact, I might get a telegram from Pete Rozelle today on this thing. But I believe in this drug.

We had a guy, a running back, and I will just cite this one more example because I know the testimony is getting long, but we had a running back, the first game he finally had become a starter. His name was Haskel Stanback. He sprained his ankle. He worked hard and was named a starting tailback for the 1978 season. We went into the Houston Oiler game and in the third quarter he chipped a bone and tore ligaments in his ankle. They diagnosed a bone chip and torn ligaments. He was going to be in a cast for 6 weeks. He was put on injured reserve.

If anybody knows anything about a cast on your ankle, it will take another 4 to 5 weeks before your leg is really well again. So in other words, he is really going to be done for the season.

They told him to take his gear home. He was heartbroken because here is his chance, his opportunity, to play. I said, take this stuff home and put it on all night. I said, wake up every hour and put it on. He did that all night. He came in Monday with no swelling in his ankle. The doctors could not believe it. They went to X-ray it again. The bone chip was still there. They still contend that there was damage done.

We had Tuesday off. They said, we will wait until Wednesday to see what happens. Haskel put this on Monday and Tuesday and came back Wednesday and was walking. He played the next Sunday against the Los Angeles Rams.

Availability in our business is the most important thing to an athlete. If you get hurt in training camp, your income, your lifetime, everything that sustains your income can be yanked out from underneath you just by an injury.

This drug is not by any means—and I think probably the word miracle drug has hurt it—but I will tell you what it does do. It enhances and increases the time to getting you back to work after an injury. Not only do athletes sprain ankles and hurt shoulders and ankles, but people fall down stairs, sprain their ankles, but they don't know anything about this drug. That is a crime.

I think it is up to this committee and to all of us to see to it that whatever has held up this drug, the bureaucracy or whatever it is, it is a great injustice to the American people. Thank you.

The CHAIRMAN. Thank you very much. That is a very graphic and vivid statement that you have given us.

Now, then, I suggest that we question the four witnesses who have just testified, Dr. Jacob, Dr. Scherbel, and Mr. Reedy and Mr. Jones. I will start with Mr. Ford.

Mr. FORD. Would it be possible for members of the committee to maybe get a bottle of DMSO and check out this smell? I am having a cup of coffee, but I would still like to know what the smell is like.

The CHAIRMAN. Mr. Lloyd.

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Mr. LLOYD. Thank you, Mr. Chairman.

I saw your presentation on "60 Minutes," Dr. Jacob, and I was very much intrigued. I just can't believe the—well, I can believe it because you say it, but the tremendous effects it must have had on reduction of damaged tissue. As an experienced medical man, is there any clinical reason for that dramatic reduction of damaged tissue?

Dr. JACOB. Yes, in the test tube, if you have cells which are damaged by what we call osmotic stress and you add DMSO to those damaged cells, instead of those cells going on to die, those cells will be revitalized and return to a normal state.

It actually does more than relieve pain. DMSO is not just a substance that reduces pain and relieves inflammation. It actually relieves swelling and this has been demonstrated in good, basic science studies.

Mr. LLOYD. Mr. Jones' testimony about the player with a bone chip and a torn ligament who used this and within 7 or 8 days was able to suit up again is really not only dramatic but it is very difficult to believe.

Mr. Jones, I am not picking on you, but I participated, certainly not at your level of sports, but I participated at sports. I have had damaged ankles, shoulders, hands, and I have never experienced anything that I could recover from that fast. I played basketball one season and I was on crutches for 30 days with a sprained ankle because I had torn the ligament. As a matter of fact, I would have to say it was 1 year before I could really run again.

What you are saying is that the man was damaged far worse than I was and it makes it very difficult for me to believe.

Dr. Jacob, would you respond to that? I realize you were not there. Mr. Jones should respond.

Mr. JONES. Not only has that happened to Haskel, but I have had that happen to me. About 3 weeks ago I sprained my left ankle. You know how this happens. When I went down, everybody on the court heard my ankle pop. I never went and had an X-ray but I went home and put the DMSO on. Within an hour after it happened—I put it on Friday, Saturday, Sunday, went into the training room on Monday and had discoloration from the middle of the leg all the way down to the toe. I taped it and I played basketball on Monday.

When I am talking about Haskel and myself, it was not relatively pain free but I could play. That is the name of the game in our business.

Mr. LLOYD. Dr. Jacob?

Dr. JACOB. Jack de la Torre who is head of neurological research at the University of Miami and Marvin Paul from Mount Sinai are here. Jack de la Torre has done research in areas of stroke and areas that hit the elderly. I think this is something that is most important for the committee to hear.

Mr. LLOYD. I will not ask any more questions, but I would have to say the gentleman from the FDA has a long hill to climb by the time he gets here.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you.

Mr. Bonker?

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Mr. BONKER. Thank you, Mr. Chairman.

My compliments to each of the panel members. I think it is rare to have such eloquent testimony in succession, but I think it says something about your individual conviction about this issue.

Dr. Jacob, I remember you coming back to Senator Neuburger's office 16 or 17 years ago.

Dr. JACOB. I am a little older but maybe not wiser.

Mr. BONKER. But we are not making much progress.

Dr. JACOB. No, and that is sad.

Mr. BONKER. I hope you would not have to come back much longer until there is some success. We are going to hear from the FDA shortly and it will be interesting to hear their response to this overwhelming testimony in favor of DMSO.

Dr. Jacob, I was just handed a note from my staff and today our office has received three phone calls from a community in the State of Washington regarding Melody Clark, an 8-year old child who has what is known as Down's syndrome.

The message says this: At 11 months she was typically unable to stand or walk, had protruding tongue and all the other symptoms. Her parents heard of Dr. Stanley Jacob and went to Portland to try DMSO on her. Today Melody is a miracle child for the entire community. She walks, runs, talks, reads, spells well, her teeth are developing almost normally. Her tongue does not protrude. Are you familiar with this case?

Dr. JACOB. Yes, I know Melody well. She is a typical Mongoloid in whom we began treatment at 11 months. She is now 8 years old. She is still a Mongoloid, but according to her teachers in school she has made more progress than any Mongoloid child they have ever seen. She has been on DMSO for 7 years.

Mr. BONKER. Dr. Reedy, it is a pleasure to have you here not only because of your experience but because you are a prominent constituent of mine. Enumclaw is located in the northeastern section of my district. I want to welcome you, as your resident Congressman, and thank you once again for your testimony.

It seems to me that your experience has been that the application of DMSO to problems of swelling seems to bring forth some solution. We have heard about pain and other things but in this particular case you have had tremendous success with swelling. Is that a fairly high percentage of the time it works with swelling or is it 50 percent of the time? I think your testimony said 70 percent success.

Dr. REEDY. Our experience, Mr. Bonker, was that we had 70 or 80 percent of the time that the player would experience excellent reduction in the swelling as well as in the reduction of pain.

One of the points in getting a patient back to rehabilitative status is due to the swelling as well as the pain. If we can reduce the swelling quickly, the joint has more mobility and as a result the player can tolerate a bit more pain as he rehabilitates himself.

In summary, we felt the reduction of swelling was every bit as significant and even possibly more in terms of assisting the rehabilitation as was the rehabilitation of pain.

Mr. BONKER. It seems to me that from the testimony we have had today, that contrary to earlier notions that this solution works only—well, not only but exclusively on problems of arthritis, we

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find that it can be applied to swelling, it may even have some application in Down's syndrome, and scleroderma which was referred to by another witness.

Just what is the extent of or the rate of success not only in terms of application but just in the multiple afflictions that you as a doctor experience with patients? It looks to me as if there are a great many uses for the drug.

Also, let me ask, while I have my remaining minute, to Dr. Jacob or anyone, if the same two people have a similar ailment or an application, is it possible that DMSO would work successfully on one and not successfully on another?

Dr. JACOB. DMSO does not work on everyone. DMSO in laboratory experiences and experiments has the widest range of primary pharmacologic activity ever documented for a single chemical in the history of medicine. It has in the literature the widest range of potential efficacy ever documented for a single chemical in the history of medicine.

I can't repeat too often that it is just a darn shame that people are dying, losing fingers, suffering needlessly, while a game is being played, and it is a deadly game.

Mr. BONKER. Doctor, since this chemical is legalized only in two States in the country, are people who use this chemical risking some kind of legal action or criminal charges in other places where it is not authorized?

Dr. JACOB. I am not a lawyer. I just couldn't answer that question. I don't know the answer to that question.

Mr. BONKER. Let me ask Mr. Jones, do you fear taking this solution because of its illegality as far as the FDA has been concerned?

Mr. JONES. I have been threatened and reprimanded by our team physicians and our trainers. When I first came to the Atlanta Falcons they didn't know what it was. I was using it. They told me not to use it. They took me in a room and told me not to give it to any of my teammates because of fear of prosecution for giving a prescription drug without a license.

My answer to that is that I don't care about the repercussions because if a friend comes to me and they are suffering, again I become emotionally involved. If I can help someone by giving them this drug which I know after using it for 10 or 12 years, that I have not had any side effects and I can help them, like I said, this fellow who had not walked in 6 years, that to me is worth it. If someone wants to fine me, they can do whatever they want. But knowing this drug has helped somebody and I had something to do with giving him this drug, that is satisfaction enough for me.

Mr. BONKER. Dr. Reedy, did you risk persecution as a result of using this?

Dr. REEDY. There is always that concern because legal action can be taken for a justified reason. However, I worked carefully with Dr. Jacob and got the medicine only from him and used it under his auspices. I explained it carefully to the management and to the players so each time I was about to use it, I took careful care to explain it all. So I felt I covered myself to the best of my capacity.

Mr. BONKER. Thank you. Thank you, Mr. Chairman.

The CHAIRMAN. Mr. Ford.

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Mr. FORD. Thank you very much, Mr. Chairman. Mr. Chairman, I want to just pose one question and ask four or five of the panelists to respond. First, to Dr. Jacob, I mentioned earlier that we are now faced with 30 million Americans who suffer from arthritis. I would like to know, for what medical condition do you find DMSO most effective?

Before you respond to that, I would like to just raise a question to Mr. Jones and he can respond right afterwards. Did you have any adverse side effects in using DMSO and do you know of any of your colleagues that might have had any side effects in the use of DMSO?

To you, Dr. Reedy, you mentioned earlier that as a team physician you found the drug very effective. What kinds of medical conditions did you find it most effective under? I know in a team physician, bruises, sprained ankles or bone injuries or what have you.

Another question to Dr. Jack de la Torre, who did not testify before the committee, I don't think he was afforded an opportunity, Mr. Chairman, but I would like to know what negative affects are there in the use of the DMSO?

Dr. Jacob, I would appreciate it if you would start off responding to the first question.

Dr. JACOB. Well, I think that DMSO is perhaps best known for its use in inflammations, injuries, painful conditions of the musculo-skeletal system. That includes sprains, strains, bursitis, tendonitis and arthritis and there is no doubt it is at least a very useful pain reliever in those entities.

It is life saving in severe head injuries. I think that with the animal experience that we have and with experience in two patients that if we had what ordinarily would be irreversible quadraplegia or paraplegia, which is the worse thing that can happen to someone and DMSO were given within an hour or an hour and a quarter, we might reverse an irreversible situation.

At the current rate of progress, 4,000 to 10,000 kids will be paralyzed from the neck down this year and it will be 5 to 10 years before the FDA gets around to approving it for that indication. It is unbelievable.

In terms of side effects, there is no drug which is totally free of side effects. DMSO is not. The side effects are for the most part nuisance except for the occasional patients who might be hypersensitive or allergic. There is a report in the literature on 2,000 patients in which three had generalized urticaria and some difficulty breathing. There is no doubt that an occasional patient could be allergic to the medication.

Mr. FORD. What would be the cost to a drug company for a satisfactory trial as to the effects and whether the DMSO should be placed on the market? What are the costs?

Dr. JACOB. I don't know how many millions of dollars.

Mr. FORD. Do you have any figures at all?

Dr. JACOB. No, but remember this, the big drug companies do not hold the patents on DMSO. It is inexpensive. It is competitive with patented agents that the big drug companies hold patents on. The only people who can benefit from this are the people. Unless the

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Congress does something about this, the people are not going to benefit.

Mr. FORD. Thank you.

Mr. Jones?

Mr. JONES. I have not had any side effects other than the basic smell. I occasionally, during the 6-month period when I used it regularly, maybe on the third day I would get a redness in the skin and that would go away as soon as I wiped it off, maybe within an hour. As far as our teammates that I have given the drug to, no one has had any side effects other than the same thing, some skin is more sensitive, and the smell. Those are the only side effects.

Mr. FORD. Dr. Reedy?

Dr. REEDY. My experience in utilization in my private practice outside the realm of sports medicine has been essentially nonprimarily, because I choose to use it within the confines of the field of sports medicine as I had made that decision with Dr. Jacob about it. I would say however, that I would like very much to use it in my patients with arthritis and acute ankle injuries because about 50 percent of my practice is sports medicine. So I would be very anxious for it to be released so I could use it more extensively.

Mr. FORD. I don't know whether the next witness would like to testify first, Mr. Chairman.

The CHAIRMAN. As soon as we finish questioning the four, then we will call Dr. de la Torre and Dr. Paul.

Mr. FORD. I wanted one final question before the witness testifies as to what negative effects are there in the use of the DMSO.

Dr. DE LA TORRE. I was going to talk about this in my statement, but I can answer the question.

Mr. FORD. Excuse me. I can wait until the witness testifies.

The CHAIRMAN. All right, suppose we wait for Dr. de la Torre's testimony.

Mr. FORD. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you.

Mr. Hopkins?

Mr. HOPKINS. Thank you, Mr. Chairman.

First, Mr. Jones, you are not a physician, yet you prescribed DMSO to a friend of yours on the same basis that any of us would have. I am not a lawyer, but I would be delighted to defend you in any lawsuits that might be coming your way. We might make a pretty good team.

Let me ask Dr. Jacob, if I may, apparently DMSO has the ability to penetrate the skin rapidly, getting into the bloodstream. What if a person had been spraying roses or peaches or something and had some poison from the spray on his skin, would it carry that poison into his bloodstream?

Dr. JACOB. It might very well. It is not always wise enough to do the right thing. It obviously could. It would not carry bacteria or viruses because of the molecular weight of both bacteria and virus is too large to carry DMSO, but it might carry another chemical through the skin.

Mr. HOPKINS. Why do they use DMSO in Canada and not in the United States?

Dr. JACOB. It is prescriptive in Canada for scleroderma. They accepted the studies in Canada and FDA did not here.

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Mr. HOPKINS. Are there States in the United States where this drug can be used legally?

Dr. JACOB. Oregon and Florida have specific laws relating to it. It is prescriptive for interstitial cystitis.

Mr. HOPKINS. How can they do that without the approval of the FDA?

Dr. JACOB. The States themselves? That is a legal question which I am not qualified to answer.

Mr. HOPKINS. Thank you very much.

The CHAIRMAN. Ms. Oakar.

Ms. OAKAR. Thank you, Mr. Chairman.

All of you certainly have impeccable reputations, although Dr. Jacob, I understand some individuals who work for the Federal Government have called you certain names that are very, very unfortunate. I think that is too bad. I would like to pursue something you just mentioned, Dr. Jacob, that was implied on "60 Minutes" last evening which I watched as I am sure millions of other Americans did. That is the question that one reason that this has perhaps not been approved is because it doesn't cost much to produce. Would you like to pursue this a little more?

I have had individuals who have done experiments with respect to cancer research who have told me that once they complete their research and the drug companies want to buy the rights to their research, they are not guaranteed that this research will ever get to the American public so they are hesitant to give up the research.

Dr. JACOB. Well, depending on which figures one reads, in Science a few months back there was a figure given of something over $50 million from the onset to final approval of a drug for its multiple uses. Now if one is dealing with an agent on which you do not hold patents, you would naturally be reluctant to invest a large sum of money in gaining approval because you would not have the protection once you gained the approval. So I think this is a consideration.

The drug companies do not hold the patents on DMSO. It is like ether. It was known for 600 years before it was learned that it is an anesthetic. DMSO was known for 100 years before it was known it had immediate medicinal properties. It has worked against it.

Ms. OAKAR. You have been very courageous, and I would like to ask you, and I intend to ask the FDA the same thing, would you say that money talks?

Dr. JACOB. Yes.

Ms. OAKAR. Drug lobbies have an impact on whether we are getting the various types of medications to our people.

Dr. JACOB. I have been asked, is DMSO the medical Watergate, I cannot answer that. I do not know that there is a conspiracy. I do know that this is a safe effective drug which is not available to people.

Ms. OAKAR. Doctors, thank you.

Doctor Scherbel, of course those of us from Cleveland are very proud of the Cleveland Clinic. We know of your national and international reputation as well. You mentioned that you have done some studies with respect to this DMSO, and yet these were not acceptable to FDA. What does it take? If you give them case-by-

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case studies, what do you have to do to satisfy them? You are a noted expert in this field.

Dr. SCHERBEL. Ms. Oakar, today drug studies are becoming more and more complex. I just came back from a meeting in San Francisco where we had symposia after symposia on design and drug trials. The problem today is that FDA is demanding very sophisticated drug trials that take months, may take years, thousands of dollars. This is the direction in which we are going.

Many times it is very frustrating because one cannot conform to FDA demands. This is exactly what has happened with DMSO. We can't double blind this drug. It smells and one can taste it. If you have a patient who has been taking it and you touch that patient's skin, you are going to taste it. So there is no way of blinding this study.

One of the other things I didn't bring out, maybe Dr. Jacob implied it, it is a very unique drug. There is no drug similar to DMSO that has ever been used in the history of medicine. I am not criticizing FDA, but FDA has no experience with this drug. Moreover, FDA consultants who evaluated DMSO, had no experience with the use of the drug.

Ms. OAKAR. In all humility do these investigators have the credentials that you do?

Dr. SCHERBEL. I can name many, many——

Ms. OAKAR. Do any of the doctors there?

Dr. SCHERBEL. I know many investigators who think DMSO is a drug that should be approved immediately. I know just as many good people, and you will probably hear some this afternoon, who disapprove strongly of the drug. So there is an individual opinion. You can bring people to this committee hearing who are pro-DMSO and you will find some who are anti-DMSO. Those authorities biased against DMSO are unable to show studies where DMSO has failed. Their bias is made up of impressions about the smell or the skin irritation or they didn't find it effective in relieving all the pain in a patient with arthritis. There are some investigators who will never accept DMSO. If this drug is released for clinical use there will be people who will benefit and others who won't. This is typical of all drugs.

Ms. OAKAR. You mentioned that when you are attempting to treat people with various forms of arthritis, that you try a variety of ways, that none of them are perfect. You mentioned specifically aspirin and the fact that in some cases it has a very detrimental effect on older Americans, and in fact, it can cause impaired hearing.

We have a person on our staff with a master's in gerontological nursing who checked with the medical staff at Case Western about this—that a low but consistent use of aspirin can produce a low plasma vitamin C level and that is counterproductive to treatment of, let's say rheumatoid arthritis.

In our evaluation of what kinds of medication older people are given, which in many cases affects the poor elderly, the most frequent type of treatment given to older people in the 200 or more people that we interviewed was aspirin. Yet, on my little bottle of aspirin, there is nothing that says anything about harmful side-effects. It is supposed to be the cure-all. The only thing it says that

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is negative is "keep out of the reach of children." Can you comment on why, if aspirin has such negative effects in some instances, why the elderly are just passed over by being given this so-called cure-all? Why they are not given the opportunities for varieties of types of individual treatment that apparently your patients have available to them?

Dr. SCHERBEL. Ms. Oakar, many of the things we are learning about aspirin we are learning about now by carrying on sophisticated studies. You must realize that aspirin has been around for 100 years. When I first came out of medical school we probably had aspirin and thyroid extract and digitalis and beyond that there were not many other drugs. Aspirin has always been recommended in large doses for patients with arthritis and the larger the dose, the more effect one would get from the drug. If you didn't get your effect, you were not taking enough medication.

Now we know that all this is wrong because today there are sophisticated studies using gastroscopy and showing that only a few tablets of aspirin may cause gastric erosions. Normally, they heal up and there is no problem.

But for people who don't have normal blood coagulation, who drink some alcohol, these erosions further ulcerate and bleed; here is where there is a problem indeed. I am a strong advocate of aspirin. What I am trying to say, is that any analgesic drug you mention may cause difficulty, or toxicity. Prophyxene is being criticized as are all other pain relieving drugs. So where do we go? Should we use drugs that are addictive? Do you want to do this? No.

It is now known that elderly people don't metabolize drugs as young people. So what do you do about this? Do you give multiple drugs to elderly people that can result in drug interaction? These are things we are learning today that we didn't know before.

When authorities become highly critical over DMSO, that can be used effectively in such a simple way, there is need for clarification of the problem that exists in the treatment of chronic pain.

Indeed, of all the drugs that I use, I would want DMSO among the drugs that I use commonly in the treatment of pain. Frequently, one cannot give one drug to a patient and get an excellent relief of pain in diseases which we were talking about. Arthritis is not simple. If a patient with arthritis improves quickly while taking some simple drug, my impression is that arthritis was not serious. I am talking about the serious illnesses, progressive arthritis or scleroderma with persistent ulcers, or impending amputation.

The controversy that exists over clinical effectiveness of DMSO is not well founded—clinical effectiveness may be variable in different patients. If toxicity is consistently minimal, the drug should not be restricted from use in clinical practice. It is my opinion that clinical effectiveness of DMSO can be decided with complete satisfaction if the drug is made available to the practicing physicians. The number of patient complaints about pain and the number of phone calls to the doctors office will decide quickly whether or not the drug is effective.

Ms. OAKAR. I want to thank you, Doctor, and commend you for the wonderful work that you are doing. I am sorry it is somewhat

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frustrated at times by the Government bureaucracy. Maybe we can help.

Thank you very much.

The CHAIRMAN. Mr. Hopkins had a question.

Mr. HOPKINS. Thank you, Mr. Chairman.

Gentlemen, I have always believed that frankness makes for long friendships, and I think you have been frank here this morning and I appreciate that. Dr. Jacob, you stated a crime is being committed. Who is committing that crime? Is it the FDA? Is it the drug companies? Are the drug companies dragging their feet? Who are the criminals that you are talking about?

Dr. JACOB. I think that probably the major criminals would be the people in the FDA.

Mr. HOPKINS. Thank you very much.

The CHAIRMAN. Mr. Mica.

Mr. MICA. Thank you, Mr. Chairman. I hate to start out on a note of calling representatives of our Government criminal. Each of the doctors who testified, I understand, are proponents and supporters of DMSO, is that correct? Do any of you have any ties or any involvement in any company or any background that would lead you to be involved in this other than your medical profession? Who makes DMSO?

Dr. JACOB. Crown Zellerback Corp.

Mr. MICA. They are a paper company. Are they located or involved in any of your clinics or research?

Dr. JACOB. No, they are not.

Mr. MICA. You indicated, as I say, that all of you are supporters of this drug, although, Dr. Scherbel, you indicated that you disagreed to a certain extent with Dr. Jacob's comments with regard to whether or not fingers had to be amputated.

Dr. SCHERBEL. Severity is not this bad in all cases.

Mr. MICA. Do any of you disagree with comments of the others that have been made here today? For instance, Dr. Jacob, you said, and I am not quite sure of the quote, but maybe you can restate it, this has the widest range of efficacy in the history of medicine.

Dr. JACOB. I said it has the widest range of primary pharmacological actions ever documented for a single chemical in all medical history.

Mr. MICA. You also indicated that the use of this medication could cause the reversal of what would later turn out to be irreversible conditions?

Dr. JACOB. That is what I said, yes.

Mr. MICA. And there is no disagreement on that?

Dr. SCHERBEL. I didn't hear your question or your comment?

Dr. JACOB. I said it could cause a reversal of what could be an ordinarily irreversible condition and that is the central nervous system.

Mr. MICA. There is no disagreement? How many countries? I understand Spain was very heavy into utilizing DMSO and they withdrew it from the market. How many countries are using it, do we know?

Dr. JACOB. United States, Canada, Great Britain, Ireland, Germany, Austria, Russia, and parts of South and Latin American.

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Mr. MICA. When you say prescriptive, I gather what we are talking about today is to make it prescriptive for a broader range of uses?

Dr. JACOB. I would like to see it prescriptive for topical uses for everything and prescriptive for head and brain damage in the United States.

Mr. MICA. In other countries is it more limited in its use or more widespread?

Dr. JACOB. It is more limited in the United States than in some countries. It is more widespread in the United States than in some countries where it is not prescriptive.

Mr. MICA. Do we have, with regard to other drugs, international agreements to utilize the basis of their scientific testing and analysis as a basis or a portion of our approval process for drugs in this country?

Dr. JACOB. That would be a question that would be best answered by the FDA.

Mr. MICA. I will reserve that for the FDA. I know the answer to that. What I am leading up to, Mr. Chairman, if I may with all of this, I am a layman and I don't have the answer to whether or not this really does everything that is indicated that it will do. But I have had 12 years of background in health legislation. I think that we are seeing a classic case being built for a total review of FDA policy, of the laws that we as a Congress have enacted and for what I have termed for many, many years a lack of affirmative action on the part of our Government in bringing to the market drugs that may—and I say may because I don't know—that may be of service to large numbers of people.

I can cite example after example. You may remember the papaya extract used in injections in the spine. They did a double blind study and found that water cured as many people as the papaya extract and they took the papaya extract off the market. But in my mind the result was that water could help cure people with certain spinal problems. The FDA didn't rule on that. They simply ruled it could not be used.

We have had these cases and I dare say with this particular substance we will see other substances, maybe of more limited use, come to the attention of this committee that are suffering the drug lag that is occurring in this country. The statistics on drug approval, drug lag in this country are among the worst in the world.

Again, I reserve comment and judgment on the use of this particular drug, but I do think we are building a case and maybe it would be appropriate for our committee at a future date to look at the entire FDA approval process and maybe propose an affirmative action plan, because to my knowledge no Government agency will follow up on a drug that is not profitable. As Ms. Oakar said, any time they come up with a drug that is not profitable or not in widespread use, the drug companies do not pursue it and our Government does not.

My last question: Is NIH doing any research on this?

Dr. JACOB. NIH has invested a few hundred thousand dollars in DMSO research, but not on a large scale.

Mr. MICA. Thank you.

Thank you, Mr. Chairman.

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The CHAIRMAN. Thank you.

Perhaps before you came in today, Representative Symms had testified that he has introduced legislation to review the Food and Drug Administration's function, to re-examine it in the Congress, and see whether or not it does need the kind of re-overhauling that you were speaking about.

Mr. MICA. Mr. Chairman, I had the opportunity to read Mr. Symms' testimony. I might say, over the past few years I have seen a number of these bills introduced and all of them, I believe, with good intent. I don't know what our agenda is as a committee. Knowing that we have the research abilities that we have had in the past, and the impact on the House, I hope we might look into one of these pieces of legislation.

The CHAIRMAN. I think that is a very good suggestion and we will certainly give it very, very careful consideration, Mr. Mica.

I just want to ask two or three questions. In the first place, Dr. Jacob, can you tell us so a layman can understand it, what does DMSO do?

Dr. JACOB. It does several things. One is that it relieves pain by blocking the small fibers and nerves which carry pain impulses. Second, it reduces inflammation, reduces swelling. Third, it actually improves blood flow to an injured portion of the body. Fourth, it tends to soften scar tissue. Fifth, it is a diuretic. Sixth, it tends to enhance the action of other drugs. It is what we call a cholinesterase inhibitor which means it aids impulses between cells, particularly in the brain. It is the only substance known to man which will protect against heat damages, against freezing damage, against radiation damage and against ultrasonic damage, the only substance known to protect against all those forms of injuries.

The CHAIRMAN. Does the Food and Drug Administration make a distinction in authorizing the use of drugs as prescribed by a physician and those available to the public over-the-counter? When I was a boy, Sloan's liniment was part of everybody's household. You didn't get a doctor's prescription, you just used it if you wanted to. Do you make a distinction between using something like that and the use of a drug by the prescription of a doctor?

Dr. JACOB. Yes they do. They make a distinction between prescriptive agents and over-the-counter. Here this morning was a man by the name of Bud Fenesterwald who, interesting enough, wrote the Kefauver-Harris amendments. He told me any similarity between what was intended and the way the FDA is implementing them is purely coincidental.

The CHAIRMAN. I asked that question because you had testified that out of a large number of uses that only in two or three cases was there an allergic reaction of a serious nature. I believe Mr. Jones said that sometimes you got a little bit of reaction or something. But Mr. Jones, you had no serious skin rash at any time?

Mr. JONES. No.

The CHAIRMAN. You mentioned, didn't you, two or three serious cases?

Dr. JACOB. Yes. There are reports of patients who are allergic to DMSO.

The CHAIRMAN. You mentioned one instance where it was hard for the patient to breathe.

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Dr. JACOB. That is true.

The CHAIRMAN. How many cases of that were there?

Dr. JACOB. There was a report of 2,000 patients and, among the 2,000, three had a generalized body rash and two had difficulty breathing, but they responded rapidly to treatment.

The CHAIRMAN. Did the difficulty in breathing pass away reasonably soon?

Dr. JACOB. Yes; it did.

The CHAIRMAN. And also the irritation of the skin passed away reasonably soon?

Dr. JACOB. Yes.

The CHAIRMAN. Were those cases where you would say there was an allergy to DMSO on the part of that patient, who used it and got that reaction?

Dr. JACOB. I would say there was a hypersensitivity to DMSO in those patients, yes, sir.

The CHAIRMAN. Could such a reaction be avoided by patients if they were going to use it without the advice of a doctor by using a small amount to see if they got any allergic reaction?

There are some people allergic to aspirin or penicillin. If they take an antibiotic shot, they always ask you are you allergic to something like this.

Would the use of a small amount indicate whether one was allergic or not?

Dr. JACOB. It is very difficult to detect sensitivity to DMSO by using a small amount. We have tried this without success.

The CHAIRMAN. I see.

Well, was the breathing difficulty severe enough to threaten suffocation and frighten the patient?

Dr. JACOB. The breathing difficulty was severe enough to require the use of epinephrine. The patients survived. There is no question but that any drug which does good has a possibility for doing bad, and DMSO is not an exception.

The CHAIRMAN. I want to ask each of the four witnesses whom we are examining now—Dr. Reedy, do you know of any instances of adverse effects from the use of DMSO and, if so, what was the nature of that reaction?

Dr. REEDY. I know of no significant side effects in any way except those of redness of the skin, which were quickly reduced by the use of any kind of cream. But there were no so-called anaphylactic reactions or spasms in the throat or difficult breathing of any kind.

The CHAIRMAN. Now, Dr. Scherbel, have you known of any serious dangerous reaction experienced by anybody who used this material?

Dr. SCHERBEL. Nothing serious, Mr. Chairman. I have seen some itching, a few patients with hives which have subsided rapidly. I have seen one or two patients who felt drowsy, more so than they ordinarily would have after using it. That is about the extent. I think one or two mild headaches.

Now, whether these are really related I don't know, but what happens if we use the drug and the method we have discussed today in our experience is very mild.

The CHAIRMAN. One other question.

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One of you, I believe it was Dr. Scherbel, mentioned the possible efficacy of DMSO against shingles. Did you mention that?

Dr. SCHERBEL. Yes. Acute herpes oster. I think we reported a few cases in our regular reports 10 years ago. Acute herpes oster is responsive to DMSO alone in a high percentage of patients.

We have some patients who don't feel that it really did shorten the course of their illness, but the acute vesicular lesions dry up rapidly, but what is most interesting is that we have never seen a patient with acute herpes oster who continued to have pain after the acute phase of the illness has subsided.

As you know, that is one of the bad complications of shingles. Here it is a disease usually of the aged. I think this drug should be at least approved for this type of condition.

The CHAIRMAN. You apply it to the body?

Dr. SCHERBEL. Just over the lesions, yes.

The CHAIRMAN. Well, I can say I hope it is not a——

Dr. SCHERBEL. Truly a real indication. I know FDA will say if this is an indication, why hasn't somebody sent a request to study the drug for oster. The whole problem——

The CHAIRMAN. The doctors say that there is no cure for shingles. My mother had it many years ago. It is just one of those things you had to forget about apparently.

Dr. JACOB. DMSO plus IDU is prescriptive in Great Britain and Ireland for shingles.

Dr. SCHERBEL. You don't need the IDU. You can just use DMSO on shingles. There is a very desirable effect.

The CHAIRMAN. I am advised by the staff that it is legal in England to use DMSO in treatment of shingles.

Is that correct?

Dr. JACOB. That is correct. It is prescriptive.

The CHAIRMAN. I am sorry. We will have to run over and vote. We will be right back. It will be 15 or 20 minutes before we can get back.

[Brief recess.]

The CHAIRMAN. The committee will come to order, please.

We understand Dr. de la Torre has to get away. If we may, Dr. Paul, we will call Dr. de la Torre as the first witness.

Dr. de la Torre is associate professor of neurosurgery, University of Miami School of Medicine, which I am very proud to say is located in my congressional district.

Incidentally, I have an honorary degree from the University of Miami, so I am pleased to have that further identification.

Dr. de la Torre holds a doctorate in science from the University of Geneva, and an M.D. from the University of Juarez, Mexico. He has done experimental research in various applications of DMSO in spinal cord, head, and cerebral stroke injuries in animals since 1971.

He is presently investigating the use of DMSO in the regeneration of the central nervous system in animals. Dr. John Marlin, chief of neurosurgery of the University of Chicago School of Medicine has made applications of Dr. de la Torre's findings toward the use of DMSO in humans.

We are pleased to have you, Dr. de la Torre. We will be glad to have your statement. If you have a written statement, we would

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prefer that you put it in the record and let it appear there in full, and that you summarize your knowledge of this subject.

Whatever you prefer to do, we would be glad to have you do.

STATEMENT OF DR. JACK DE LA TORRE, ASSOCIATE PROFESSOR OF NEUROSURGERY, UNIVERSITY OF MIAMI SCHOOL OF MEDICINE

Dr. DE LA TORRE. Thank you, Mr. Chairman.

Ladies and gentlemen, I am going to try to be brief in my statement because I know you may have some additional questions of myself or the other witnesses.

By way of background, I would like to give you a capsule summary of our experiences with DMSO, which span back 10 years and include more than 500 animals, four different animal species, and various models of neurological trauma.

We began these experiments in 1971 when we were looking for a drug that might be effective for head trauma. The following year we applied these observations to spinal cord surgery.

I would like to summarize the effects and properties that DMSO had on these two model injuries.

First of all, we noticed that there was a significant reduction of intracranial pressure, and I may point out that this is one of the devastating consequences of head injury. If DMSO were effective only for decreasing intracranial pressure, it would still be a very useful drug.

Following these experiments, we also noted that in our head injury model, there was an improvement in cortical flow within 30 minutes after the animal had reached an end point.

There was also an increase in the carotid flow to the brain. The carotid arteries are two blood vessels that bring blood to the brain. We noticed there was a significant increase in the carotid flow in the DMSO treated animals as opposed to those animals that were treated with something else.

DMSO also appeared to stabilize the electroencephalogram. In these model injuries, the animals are brought to a point where the electroencephalogram becomes flat. This is a point preceding brain death and eventual death of the animal.

Following 10 minutes after the administration of DMSO, the electroencephalogram returned and was active.

DMSO also stabilized blood pressure in these animals. This is an important point because following head injury or spinal cord injury there is always an increase in blood pressure in both animals and humans, and if you cannot control this blood pressure, it may lead to death.

There was also an increase in the respiratory pattern of these animals. The animals appeared to breathe deeper and faster. This again is a good effect because in many brain injury patients or animals, respiration becomes very shallow and may eventually stop.

We confirmed the data that Dr. Jacob had shown some years earlier on the urine output. DMSO increased the urine output by five times when you compared it to other treatments.

These initial experiments then led us to expand our observations on a permanent spinal cord injury model and on cerebral stroke.

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Now, these two injuries are devastating. In cerebral stroke if no treatment is applied, the animal will either become comatose or lethargic or die. In the case of permanent spinal cord injury, if no treatment is applied, the animal will be permanently paralyzed. We noticed that after the administration of DMSO—and all these doses were given intravenously—that there was an increase in spinal cord blood flow to the region of trauma.

This is a very important effect because one of the first things that happens after trauma to the spinal cord is that there is a reduction of oxygen and blood flow because the vessels constrict or shut down the spilling of enzymes and other materials into the tissue.

The tissue then swells up. If you don't apply some treatment it may eventually lead to paralysis.

We also noticed in our cerebral stroke models that the same thing happened, that is, there was an increase in cerebral blood flow in the area infarcted.

There was a significant reduction of brain edema. This is an accumulation of water in the brain. The water in the brain accumulates as a result of trauma. The trauma lyses many of the cells and they spill out their contents into the tissue, increasing water content and thus pressure in the brain.

Now, because the brain is encased in a bony box, the cranium, if it has no release of the pressure being built, it will eventually compress important centers in the medulla and lead to death. So, DMSO significantly reduced the brain edema that was present in these animals.

The CHAIRMAN. Excuse me just a minute. You mean it will have the effect of drying up the water?

Dr. DE LA TORRE. Yes, precisely. We have theorized many things about the action of DMSO. Indeed, it would take me several hours just to explain some of these properties to you. I don't think that we have the time, because it is an extremely complex picture, biochemically.

But, it does appear to pick up water, carry it to blood vessels, and then remove it from the brain. So it really dries out the brain, in a sense.

The CHAIRMAN. Would it have that same effect upon blood that might seep through the cranium, the cavity that you were talking about?

Dr. DE LA TORRE. Well, the blood in itself is not harmful in the sense that there is something toxic about it. It is simply the volume that these blood cells contain. When they spill out of their blood vessels, they start compressing the tissue itself.

Now, if they happen to be compressing the tissue in an area that is critical to survival, naturally irreversible damage will occur, or even death.

The CHAIRMAN. I recall one case where as much as a half a pint of blood accumulated on either side of that cranial cavity that you are speaking about, which required an operation.

Now, would there have been a possibility that this might in some way or another have been able to dispense with that blood?

Dr. DE LA TORRE. Well, I should explain that there are two types of injuries when we deal with stroke. One is the hemorrhagic

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stroke, that usually occurs following a rupture of a blood vessel; for example, an aneurysm, or high blood pressure in a individual.

The second type is the one that we have worked on, which is the infarction type. In this model, we simulate a cerebral stroke by occluding one of the major vessels to the brain, and although there may be some spillage of blood, it is not massive in that sense.

So, the experiences that we have are merely with the accumulation of water in the tissue in the brain, which is very similar to blood because it still takes space and you still have to get rid of it if you want the subject to survive.

However, some experiments have been done in humans at the University of Chicago and they show that even the spilling of the blood into the brain can be reduced by DMSO. How it does this, no one really knows for sure.

We noticed in our stroke model that all our animals following occlusion of this major blood vessel had a narrowing of the blood vessel after 17 hours. When we took the clip off this blood vessel to allow the flow to return, this narrowing was still present, except in the DMSO-treated animals the narrowing was not present in this major vessel.

Because of this, we theorized that the perfusion of the blood vessels in the posterior area of the brain which is not supplied by this particular blood vessel was better, simply because DMSO kept this blood vessel from narrowing down too much.

How it does this again is speculation.

So these findings, then showed that DMSO was highly more effective than other treatments that are presently used for stroke, for spinal cord injury, and for head injury.

In addition to this, DMSO appeared to protect nerve cells from the actual physical disruption that occurs following injury. It did this better than the other treatments used. This was verified by a number of tools, including observation through the electron microscope and observation through the light microscope.

The picture of how DMSO works in these systems is still highly theoretical. Chemically, we still don't know what is happening. In the short time that I have to summarize all this data, I don't think I could give you an intelligent overall view, so you could understand biochemically how DMSO is acting.

However, several facts do stand out, first that DMSO is extremely effective in preventing the paralysis that may ensue in these animals following trauma to their cord; second, that DMSO can prevent or reverse many of the pathologic signs that are seen after brain trauma.

Third, and not least important, is that DMSO can prevent the severe effects seen after an embolic brain stroke. This is an area that may affect half a million people in the United States alone.

Now, we were curious to find out if there was some toxicology to this drug. Although some toxicity studies have been done before on various animal species, no toxicity studies had been done on the drug after intravenous use for an acute period of time.

So, we took a series of rhesus monkeys that are phylogenetically very close to man, and injected high doses of DMSO intravenously for 9 days. Before and after we tested these monkeys for their

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serum chemistries, their cardiovascular responses, their neurological signs, and their ophthamological changes, if there were any.

Following the toxicity studies, which took 18 weeks, we concluded that there were no significant changes in the serum chemistry at any time during the observation period. These changes, of course, were compared to a control series of animals.

There were no changes in the urine, and there were no neurological changes. There were no changes in the cardiovascular responses. There were no ocular changes. We were curious to see if there might have been some changes in the refraction or translucency of the lens, since some years previously this had been reported to have been a problem in rabbits.

One of the ophthamologists reviewed these animals before and after DMSO, not knowing which animals had received the drug, and it was concluded that there were no changes at all in the eyes of these animals.

Then following the experiments, the animals were autopsied and the tissues examined histologically. No pathologic changes in the histology were found.

So, our conclusion then is that DMSO, at least as far as these events were concerned, is an effective and relatively nontoxic drug as used intravenously.

Our results in spinal cord injury, brain trauma, and stroke have been confirmed by at least three different groups of investigators in other parts of the country for each project.

We feel that DMSO is a highly effective drug in central nervous system injuries that we have mentioned, and it may open possibilities to other neurological disorders that affect brain swelling.

For example, in children there is a syndrome—Reye's—where there occurs an increased intracranial pressure, and often surgery or drug treatments are not very effective. So, it does open the door to other neurological disorders.

I feel that at this point, and with all the accumulated evidence at hand, that perhaps the time has come to approve use of DMSO because it will make it easier for clinicians to use it for their studies.

Right now, if the clinician wants to use it in a clinical study, he has to go through NDA and FDA approval, and it takes a long time to get it and there is a lot of paperwork.

Some clinicians are put off by all this paperwork, and they will not do a clinical study under those conditions. But if the drug is approved, I believe that it will enhance our understanding of how it is working and may provide clues to even better drugs than that.

The CHAIRMAN. Doctor, why, in your opinion, has FDA turned down the approval of this substance and delayed so long its approval of it?

Dr. DE LA TORRE. I don't know. We presented our data to them and the experimental evidence was there for anyone to review. And of course they make their decision as to whether or not the drug should be approved.

The CHAIRMAN. Did you have any adverse reaction from any of the animals you used it upon?

Dr. DE LA TORRE. No. There is no significant toxicity involved in this drug, even with high intravenous doses. I believe this has been

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substantiated in preliminary studies in humans who are brought into the hospital with severe injuries.

The CHAIRMAN. Have you anything else to add to your original statement, Doctor?

Dr. DE LA TORRE. No, sir.

The CHAIRMAN. Well, we are very pleased to have you.

Do you think that DMSO might have any efficacy against brain tumor?

Dr. DE LA TORRE. A brain tumor is a mass that is pressing on the brain. I seriously doubt that DMSO would dissolve that tumor.

However, it might be useful to use DMSO following removal of the tumor and the consequences related to the surgery, where one might get swelling of the tissue after the excision of a tumor. So it might be useful in that sense.

The CHAIRMAN. I just wanted to ask one other question. Did someone say that it might have some salutary effect upon reducing high blood pressure?

Dr. DE LA TORRE. Only so far as a brain injury is concerned. For example, when the brain is traumatized, there is a condition that can result in increased blood pressure.

We don't know exactly what mechanisms are involved there. But besides affecting the blood pressure, it also affects the lungs and other organs. The perfusion to the brain is diminished. If we find a drug that can increase this perfusion, it can prevent its lethal or devastating damage to the brain cells and possibly to cells in other organ systems.

The CHAIRMAN. Thank you very much.

Would my colleagues forego just a moment and let's hear Dr. Marvin Paul. Dr. Paul is a staff member of Mount Sinai Hospital, Toronto, Canada, and a former team physician for the Toronto Maple Leafs.

Dr. Paul graduated from the University of Toronto Faculty of Medicine in 1957. He is presently a general practitioner. In the early 1970's, Dr. Paul was the clinical investigator for the Health Protection Branch of the Canadian Ministry of Health and Welfare to research the use of DMSO on humans.

May I, without immodesty, Dr. Paul, mention the fact that I have the honor to have an honorary degree from the University of Toronto.

Dr. PAUL. A good university.

The CHAIRMAN. We welcome your statement.

STATEMENT OF DR. MARVIN PAUL, TORONTO, CANADA, FORMER TEAM PHYSICIAN, TORONTO MAPLE LEAFS

Dr. PAUL. Basically I came here to talk about DMSO and its use in soft tissue injuries, particularly sports injuries. But now that you mention this work that I did early in the 1970's, that is, severe chronic rheumatoids and scleroderma. I did work with a small number of patients with scleroderma, and it was based on my work that the Food and Drug Directorate in Ottawa approved the use of DMSO in the treatment of scleroderma.

This drug is now available, made by a pharmaceutical house called Frank Horner, Ltd. and is marketed as a drug called Kemsol. It might be of interest to you here in the United States;

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Frank Horner, Ltd. is a subsidiary, a Canadian subsidiary, of Carter Wallace, Inc.

On the other hand, whereas in the United States it is approved for treatment of interstitial cystitis, it is not approved in Canada. As far as any other condition—we are in the same boat as you—unapproved.

Now, basically the work that I was referring to at the beginning in sports injuries came about in the year 1965 when clinical research was going on at a frantic pace. In 1966, I reviewed the results I obtained with DMSO treatment for these various soft tissue injuries in 1965 and compared them with similar injuries treated with conventional forms of therapy in 1964 and 1966, using the parameter of disability time as my guide to efficacy.

Now, remember these are professional baseball players. It was 1965 when there were not these fancy 5-year contracts you read about today. These were 1-year contracts, and the next year's contract was dependent upon the present year's work, and the motivation was to get out there and play to enhance their financial prospects for the next year.

The results were startling. The disability time was a small fraction in 1965, using DMSO treatment, compared to the conventional treatment used in 1964 and 1966.

Now, I am quoting a short paragraph in a paper I wrote in 1966 that was presented at the Vienna symposium that year. It is very short.

> The significant superiority of DMSO therapy in the treatment of all these types of acute soft tissue injuries in athletes was quite obvious. It would not be an exaggeration on the part of the author to state that dimethyl sulfoxide was the most important therapeutic agent available to him in these types of injuries so frequently encountered by athletes in competitive sports.

To that I may add it is as pertinent in 1980 as it was in 1966.

Now, as Dr. Reedy pointed out——

Mr. PEPPER. I will have to interrupt you. One of the problems we have here, during the time that the House is in session, is constant interruption with rollcalls. If we don't go answer and vote, folks back home will think we are fishing today, instead of being here on our jobs.

I wonder if it would be possible for you gentlemen at the table here now to come back after lunch, and you finish, and then also the witnesses that are scheduled for this afternoon—the Food and Drug people and Mr. Bennett and Mr. Baum.

We will recess now until 2:30 p.m.

AFTERNOON SESSION

The CHAIRMAN. The committee will come to order, please.

At the time of the recess, Dr. Paul was giving a statement.

Doctor, we welcome you and you may proceed.

Dr. PAUL. I may be a bit repetitive at the beginning because I forgot exactly where I was.

I was talking about the opinion I have that DMSO is far superior to any other form of therapy for soft tissue injuries and using as my parameter of the disability time.

I think this is as valid as a double blind study in view of the circumstances used in compiling this data and evaluating it.

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The double blind study, as has been outlined in the past, in my opinion is impossible with DMSO because of its properties.

The decreased disability time is a vital factor and speaks for itself. For the life of me, I cannot understand why results that one bureaucratic body, and we call it the workmen's compensation board back in Ontario, would look upon these results as spectacular, yet they are totally unacceptable to another bureaucratic body called the Food and Drug Directorate or agency. In the United States it is the agency and in Canada it is the directorate. I think it is as pertinent for one as it is for the other. I was glad that Dr. Reedy extrapolated his data and pointed out in his experience it was his opinion that this would be as valid in industrial injuries as it would be in sports injuries.

In 1965, I treated a few industrial injuries with DMSO and it was my impression that their results achieved there were equivalent to those in sports injuries. I think this is of extreme importance both from a therapeutic and an economic standpoint.

Now, I wasn't going to talk about anything else. But I would like to briefly point out several positive factors that were not brought out in previous testimony by other medical witnesses.

Dr. Jacob did not mention one other property proved scientifically without a doubt, and that is DMSO relaxes muscles. It is a muscle relaxant, and a darned good one.

One of the conditions that we see frequently in the practice of medicine is a very common condition called herniated intervertebral disc—a slipped disc. In the vast majority of cases slipped discs are a self-limiting condition.

They will clear up in 95 percent of cases no matter what you do, in spite of what you do. That is fact. All that physicians do is give symptomatic relief, waiting for nature to take its course, that is in the 95 percent of cases.

Basically I will not use painkillers unless someone is against the wall. My therapeutic attack has been directed on two fronts, the use of an anti-inflammatory agent or a muscle relaxant, or both.

Basically right now it is down to the use of anti-inflammatory agents because in order to get the muscle relaxant that is used to work on these patients, I have to use valium—the most effective muscle relaxant available—in high enough doses that you have to put them to bed because of the drowsiness side effect.

I don't like putting people to bed. Psychologically it is a bad place for them. They get too used to it. What I try to do is keep them mobile as long as I can, as best I can. I cannot knock them out, I cannot make them drowsy, and to use valium in the proper dosage for muscle relaxation one requires a dose that is going to make them at least drowsy. I just wouldn't trust that individual to drive a car, for instance, with that dosage.

DMSO combines both. It is an anti-inflammatory drug and a muscle relaxant. In the limited experience I had in 1965 treating acute discs with DMSO, the results were very, very good, better than either anti-inflammatories or muscle relaxants alone. They cleared up more quickly than I had reason to expect, far more quickly than I had seen in the past and now see with the conventional forms of therapy.

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Point blank, I myself am one of the individuals who I treated with DMSO for a slipped disc, and I can tell you point blank that it works better than anything else I have ever tried before or since DMSO therapy. I make this statement because this is a recurrent problem for me. That is a personal experience for me.

Sure, it is a testimonial, but unless one has experienced a thing, one is offering secondhand information, and it is firsthand for me, and for me firsthand information is far more valid than second hand.

One last comment I want to make; that is, about the odor side effect. I would like to turn that coin over and look at the other side of the coin.

To me, this is a positive thing in that it is a self-regulatory mechanism for the drug. Who the heck wants to walk around with stinking breath? I think the drug will not be abused because of this bad odor. Sure, this side effect is unpleasant, but on the other hand, it will get the patient off this drug as quickly as possible.

I think that is a beneficial thing. When the patient doesn't need it, they will stop it as quickly as they can. I look upon it in many ways as a positive factor.

Thank you.

The CHAIRMAN. Doctor, how extensively have you used DMSO?

Dr. PAUL. Well, in 1965, before the ban of all testing of all types I had rather considerable experience with DMSO in many conditions. May I point out it was banned at that time for safety reasons. We learned last night on "60 Minutes" that FDA now considers DMSO a relatively, if not totally, safe drug, which we felt all along.

I think I had about 200 patients who I treated for various conditions, basically soft tissue conditions, discs, things like that—about 200 patients in 1965.

The CHAIRMAN. How many serious reactions have your patients had from the use of it?

Dr. PAUL. None. No serious reactions. I have had the bad breath and the skin reactions, but never anything but mild. We had to use common horsesense in therapy. For instance, we knew in fair-haired, fair-skinned individuals you had to go easy on the stuff, because they are more prone to skin reactions.

Though my hair doesn't show it, I am very fair skinned. I got a skin reaction to it. But boy, the effect it had on my back, it was worth it. It was a mild skin reaction, but I was glad to put up with it because of the therapeutic result achieved. I never encountered any serious reaction. I made the statement somewhere down the line that I consider this drug safer than aspirin.

The CHAIRMAN. Now, Canada gives only limited permission for the use of it so far?

Dr. PAUL. Yes, just for its use in scleroderma.

The CHAIRMAN. Why do you think Canada has not permitted the general use of it?

Dr. PAUL. Well, we are into this business of the thalidomide scare still, you know. I have no concrete knowledge of this, but I think they are very, very loathe to make any mistakes. Therefore, I feel they would rather pass the buck than take a stand.

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If they are not sure, they are not going to take a stand. But I really don't understand, now that it has been acknowledged that it is safe, why they are so hesitant about releasing this drug.

Now, I went all through the safety precautions in my DMSO studies with scleroderma and rheumatoid arthritis. It was a pain in the neck. There is no question about it. Doing monthly blood scans, 3 monthly eye exams was a pain in the neck. The paperwork was awesome. That was a definite deterrent to any type of testing for me.

I really don't understand why they don't open it up. They may not be able to get the physicians to achieve sufficient numbers to justify release because of the amount of paperwork entailed.

I don't know. But there is a reluctance there, there is no question about it—in both countries, obviously.

The CHAIRMAN. Well, Doctor, I would appreciate it if you and all of you who have been on this panel could wait in the room until after you hear the Food and Drug Administration's testimony.

Can you stay that long until you have heard them? All right. If you have to go, of course we will understand that.

Mr. Bonker?

Mr. BONKER. Mr. Chairman, I just want to anticipate the FDA Director's testimony and ask Dr. Jacob if he could return to the table just a minute.

Everyone is interested in FDA's response to the overwhelming testimony that has been presented here today, particularly the eloquent statement that you presented. Just reading through Dr. Crout's testimony, it places a lot of emphasis on the National Academy of Science study in 1972.

I want you to comment on that just briefly, so we have the benefit of that when his statement is presented. Then on his last page he says there is no evidence that DMSO alters the course of any disease or is in any sense a miracle drug.

> To suggest on the basis of the evidence available to date, controlled or uncontrolled, that DMSO is a major medical advance for any serious disease let alone a variety of such diseases is misleading.

Then he concludes and says that the FDA is willing, indeed anxious—it is kind of ironic after 16 years—to approve DMSO for such uses whenever, and I am going to quote, "* * * controlled trials meeting the statutory standards are available."

Then he goes on to say that they would be happy to work with any party in developing protocols for such trials and in expediting their review.

Question No. 1, your response to the NSA study; No. 2, if the FDA is so willing and anxious to help, what is the problem with these so-called control trials meeting the statutory standards that seems to be a major roadblock in their estimates?

Dr. JACOB. Well, in terms of the National Academy of Science's report, I had the opportunity of speaking before the Academy prior to their writing their report. We furnished a good share of the bibliographic references on which they based their report.

Now, the National Academy of Sciences began their evaluation of the published literature on DMSO in the late 1971-72 era based on studies which were done in 1964-65.

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Between 1964 and 1966 and 1971–72 many of the concepts relating to controlled studies were altered so that they were in effect evaluating studies done in a period of time prior to newer techniques of controlled studies. That was one of the reasons they felt that the studies were not all that well controlled.

On the other hand, as I mentioned this morning, given indocin, had they evaluated indocin the same way, they would have come to the same conclusion because the conclusion of the house and Dr. O'Brien was that none of the studies were valid. So that there was that time frame when one worked with different criteria for control.

But if you really study the Academy report, they say that DMSO is at least as good as anything else that we have for acute shoulder, for chronic shoulder, and for acute injury. They say no better, but at least as good.

They also say that it has potential and they say in their conclusion that there is no toxicity so great as to preclude its use in any condition in which efficacy has been demonstrated.

The other point about the National Academy is that there was no one on that committee who had ever used DMSO. I had the opportunity of speaking to them. They read the literature, but they did not have experience with DMSO. I don't know if that answers your question or not.

In terms of Dr. Crout's feeling relating to DMSO not being a miracle drug, I don't like to use the words "miracle drug" myself. But as I mentioned before, there is no chemical substance with a wider range of primary pharmacological activity or a broader range of efficacy as one can find in the literature for DMSO.

Mr. BONKER. There just seems to be an institutional bias at FDA against this substance.

Dr. JACOB. I think there is, no question. I think the FDA is biased against it.

Now, the only time the FDA was not biased against it was when it was in Dr. Gibson's division. DMSO got a fair shake from Dr. Gibson and George James and John Richmond and K. C. Pani.

When the situation was changed to a different division, I no longer see that fair shake. I don't see how DMSO can receive a fair shake from the FDA the way it is now being handled.

I am discouraged, regardless of what Dr. Crout or Dr. Finkel or Dr. Gyarfas say.

Mr. BONKER. And it apparently doesn't matter who the Director is.

Dr. JACOB. That is right.

Mr. BONKER. It just remains regardless of who the Director is. He comes in and listens to his technical personnel and just more or less carries on that policy statement from administration to administration.

Dr. JACOB. Yes. I think that is what happens.

The CHAIRMAN. Ms. Oakar?

Ms. OAKAR. Thank you, Mr. Chairman.

I want to thank Dr. Paul for coming from Canada to be with us.

Dr. Jacob, for the record, we have never gotten the components of DMSO, so maybe you would like to explain very briefly.

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Dr. JACOB. DMSO is CH_3, S double bond on CH_3, carbon, oxygen, hydrogen, sulfur. A molecular weight of 78. A very simple chemical compound. It is in some ways water's alter ego.

One of the reasons it does what it does is that it combines with water. If one looks in the Random House dictionary, the two liquids on this planet given the most attention are water and DMSO.

Ms. OAKAR. We have heard so much about the smell of it. Yet, when we had a bottle up here it didn't have an odor to it.

Dr. JACOB. It is not so much the odor in the bottle. It is the way the body metabolizes DMSO, and the body forms dimethyl sulfide, which produces the odor.

Ms. OAKAR. Mr. Chairman, if I could ask unanimous consent request here. I think it would be very, very helpful to be able to ask the doctors a few questions perhaps after the testimony by the Food and Drug Administration.

The CHAIRMAN. That is the reason I asked if they could remain.

Ms. OAKAR. OK, thank you.

The CHAIRMAN. We want to thank all of you who came here in the warmest way. Dr. Paul, we especially appreciate your coming all the way from Canada to be with us. Your testimony today has been extremely valuable and we are very grateful to you.

Now, then, our next witnesses will be from the Food and Drug Administration. The first witness is Dr. J. Richard Crout. He is Director of the Bureau of Drugs with the Food and Drug Administration.

He served on the faculty of the University of Texas, Southwestern Medical School, and was professor of pharmacology and medicine at Michigan State University College of Human Medicine.

He has been with the FDA since 1971. Dr. Crout is a member of many professional organizations and a former holder of the Burroughs Wellcome Fund Award in clinical pharmacology. He is the author of some 50 research papers in the field of hypertension, neuropharmacology, and clinical pharmacology. His current professional interests are in drug regulatory systems and policy, and in public administration.

Doctor, we will be glad if you and your associates will come up to the witness table, please. Dr. Crout is accompanied by Dr. William Gyarfas and Dr. Marion Finkel.

Dr. Gyarfas is Director of the Division of Oncology and Radiopharmaceutical Drug Products with the Food and Drug Administration. He has been employed by the FDA since 1963, where he has served as Director of the Division of Surgery and Dental Drugs and Acting Director of the Office of New Drugs. He has been at his present position since 1974.

Dr. Finkel is Associate Director for New Drug Evaluations with the Food and Drug Administration. She has been with the FDA since 1963 where she has served as Director of the Division of Metabolic and Endocrine Drugs, Director of the Office of Scientific Evaluation, and has been Associate Director for the New Drug Evaluations since 1974.

Dr. Crout, we welcome your statement. If you would like to begin.

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STATEMENT OF DR. J. RICHARD CROUT, DIRECTOR, BUREAU OF DRUGS, FOOD AND DRUG ADMINISTRATION, ACCOMPANIED BY DR. MARION J. FINKEL, ASSOCIATE DIRECTOR, NEW DRUG EVALUATIONS, FOOD AND DRUG ADMINISTRATION; AND DR. WILLIAM J. GYARFAS, DIRECTOR, DIVISION OF ONCOLOGY AND RADIOPHARMACEUTICAL DRUG PRODUCTS, FOOD AND DRUG ADMINISTRATION

Dr. CROUT. Thank you very much, Mr. Chairman.

We are pleased to be here to represent the Food and Drug Administration at this hearing on DMSO. I will review the regulatory history of DMSO and then comment on the current status of the drug in this country, with particular reference to its potential value in the treatment of arthritis.

Let me say right at the beginning, however, that the fundamental problem with DMSO from our perspective is not bureaucratic opposition. I assure you of that personally and on behalf of our institution.

The fundamental problem from our point of view is the quality of the scientific information that is available to support the various claims that are made for DMSO, and that is a point I would like to emphasize in my testimony.

I want to make it clear that the Food and Drug Administration has approved DMSO for the indication for which there is evidence that meets the statutory standard. We are prepared to approve it for any other indications when the evidence comes along that it does meet that statutory standard.

The first investigational new drug application for the study of DMSO in humans was approved by the FDA in 1963. Enormous interest in the drug developed rapidly, and it began to be used widely, especially for the treatment of sprains, bruises, and minor burns.

By 1965 an estimated 100,000 patients had received the drug. No well-controlled studies were conducted, however, to document clearly that the observed effects were actually due to the drug.

This widespread, uncontrolled use of DMSO was curtailed sharply on November 25, 1965, when FDA published a statement in the Federal Register terminating all clinical use of DMSO because of toxicological studies showing that high doses of the drug changed the refractive index of the lens of the eyes in experimental animals. The agency's concern at the time was that visual damage might occur in humans exposed to the drug.

A year later this policy was relaxed to permit clinical evaluation of DMSO in serious conditions, such as scleroderma, persistent herpes zoster and severe rheumatoid arthritis, for which no satisfactory therapy is now available."

In September 1968 the FDA published a further revision, a relaxation of its DMSO policy permitting topical application to the skin for not more than 14 days for less serious disabilities such as acute musculo-skeletal conditions; for example, sprains, bursitis, and tendonitis.

This was based on a toxicological study in humans that provided a reassuring result; that is, no evidence of eye toxicity due to DMSO was found in humans.

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In light of continued lack of evidence of eye damage in humans since that time, FDA has concluded that the regulation establishing specific requirements for clinical testing on humans is no longer necessary and, thus, on September 21, 1979, the agency published a Federal Register proposal to revoke the regulation.

A final order on this proposal is now being prepared for publication. Mr. Chairman, I would like to submit for the record copies of the various Federal Register notices on DMSO that I have just discussed.

During the 1960's at least three major drug firms considered the possibility of marketing DMSO commercially under approved new drug applications but all later lost interest, presumably because of low profit potential due to the fact that DMSO cannot be patented as an original molecule.

The CHAIRMAN. Excuse me just a minute. Did I understand you to say that these three companies simply desisted in the presentation of their application? I thought some of these witnesses testified that they were turned down by Food and Drug.

Dr. CROUT. They were. But we turn down, I might say, most new drug applications the first time around, because there are usually deficiencies in applications. So that is not an uncommon thing to have happen. In this case, the firms did not come back to us.

Because of continuing controversy over the FDA's position on DMSO, Dr. Charles C. Edwards, then Commissioner of Food and Drugs, asked the National Academy of Sciences in 1972 to review all available information on the effectiveness and toxicity of DMSO and provide FDA with an independent judgment on these matters.

The academy appointed a committee of experts with six subcommittees to conduct this review. To this day, the National Academy of Sciences' review stands as the most comprehensive independent evaluation of DMSO by the medical and scientific community.

The academy basically agreed with the position of FDA on DMSO. Specifically, the report stated that there was inadequate scientific evidence of effectiveness of DMSO for the treatment of any disease, that the toxicity potential was sufficiently great that the drug should remain an investigational drug, and that controlled clinical investigations were necessary to demonstrate the effectiveness of DMSO.

Mr. Chairman, because of your committee's particular interest in arthritis, I would like to quote the conclusions in the academy's report of the Subcommittee on Connective Tissue Diseases. The subcommittee concluded:

(1) That most of the studies reviewed were of such poor quality as to be useless for its purposes.

(2) That there is no convincing evidence that DMSO has any effect in the treatment of osteoarthritis.

(3) That there is some indication that DMSO decreases pain in rheumatoid arthritis, but no evidence of an anti-inflammatory effect on that condition.

(4) That DMSO has no effect on the systemic manifestations or the progression of scleroderma.

(5) That there is insufficient evidence of the efficacy of DMSO in the treatment of gout, polymyositis, polyarteritis nodosa, Dupuytren's contracture, or ankylosing spondylitis. These are a variety of arthritic type diseases.

(6) That the varied effects of DMSO on immunologic mechanisms as studied in human and animal models seem to have little application in the treatment of human diseases.

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I would like to submit a copy of the academy's report for the record.

[The above-mentioned report is retained in committee files.]

Dr. CROUT. Since the Academy's report, drug developmental interest in DMSO has been focused primarily on two uses—scleroderma and interstitial cystitis. I should add at this point there are no new data since that time on the use of DMSO in sprains, bruises or soft tissue injury.

So, new data gathered by modern standards since the 1960's on these common disorders are not available even to this day.

Well-controlled studies have been conducted in patients with interstitial cystitis, a painful chronic bladder disorder for which no really satisfactory treatment exists. These studies have shown that DMSO provides symptomatic relief of bladder pain for this condition.

A new drug application for use of 50-percent DMSO in interstitial cystitis was granted to Research Industries Corporation of Salt Lake City, Utah, in 1978.

Research Industries Corporation also submitted in 1978 a new drug application to market DMSO for the symptomatic relief of pain and ulceration in the fingers of patients with scleroderma, a crippling disorder involving the hands and sometimes other tissues in the body.

After detailed review by the Bureau of Drugs staff and by our Arthritis Advisory Committee, this application was turned down on the grounds that the available clinical trials do not yet demonstrate that DMSO is effective for this use.

I want to point out that our evaluation process is not simply a narrow, one-person review by the Food and Drug Administration staff. This decision was taken only after careful review by an advisory committee of experts, all of which was open, and a careful review by our staff and by the management of the bureau.

So, our process involves a great deal of scientific consultation. It is not a matter of one or two persons exercising arbitrary authority.

This was not an easy decision to make, and I would like to elaborate briefly on the reason we reached this conclusion so that you may see some of the ambivalence that faces an advisory committee of scientists who have that sort of a decision to make.

The most important clinical trial on which the company relied for demonstration of effectiveness was a study in which only one hand in each patient—and by the way, the patients get ulcers on both hands—but one hand was treated with DMSO. The other hand was followed as a control.

There was a general improvement trend in the healing of ulcers of the fingers in many patients, and in a few this was quite striking. Interestingly, however, this improvement occurred in both hands in these patients with scleroderma; that is, both the treated and untreated hands tended to heal.

The company argued that the overall improvement trend supported the point of view that DMSO is effective. The firm suggested that the beneficial effect in the nontreated hand could probably be attributed to absorption into the body of DMSO from the treated hand. Thus, both hands were treated with DMSO.

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Our staff and advisory committee felt, to the contrary, that improvement of the untreated hand raised the strong possibility that the general improvement trend in the whole trial was attributable to a nonspecific effect of DMSO. Everyone agreed that the trial showed that DMSO may be effective, but few felt that the trial proved the point.

Because the statutory standard for approval of a drug is substantial evidence of effectiveness as shown by well-controlled trials, not simply the possibility of effectiveness, we are unable to approve DMSO for this indication at this time.

I think this illustrates a fundamental confrontation, if you will, between the quality of the scientific evidence available and the statutory standard for approval. Again, from our perspective, the only thing holding up an approval of DMSO for any of its indications is the availability of well-controlled trials that meet statutory standards.

It is the science that is deficient as far as DMSO is concerned.

Because of the possibility that DMSO may be useful in treating the hands of patients with scleroderma, we believe a properly controlled study should be conducted to demonstrate whether the drug is effective or not.

We have, therefore, contacted representatives of the Cooperative Systemic Studies for Rheumatic Diseases Group, which is supported by a contract from the National Institutes of Health. This is an academic group of rheumatologists, supported under a contract from NIH.

It is our understanding that a new trial of DMSO for scleroderma is being organized by the group and will be conducted in the future. This trial will be controlled and blinded in such a way as to obviate the problems of past trials.

We look forward to receiving the results of this new trial, but I must acknowledge in all honesty that a definitive scientific answer is probably at least 2 years away.

Let me turn now to the IND's; that is, the investigational applications that are on file with us. These are the applications for new research.

At present the FDA has on file 16 active investigational new drug applications for DMSO. Conditions under study include scleroderma, joint injuries and spinal cord injuries. There are no active IND's at the present time for the study of DMSO in rheumatoid arthritis or osteoarthritis.

There is no regulatory barrier to the evaluation of DMSO for these or any other indication. Our sole interest is in seeing that research on DMSO is well controlled scientifically so that meaningful data result and that studies are conducted safely under the usual ethical and scientific standards that apply to all human research.

In summary, DMSO is a solvent that crosses body membranes with ease and appears to have analgesic effects when applied locally. There is much testimonial evidence to suggest that DMSO relieves pain after local application to injured or inflamed tissues.

This is an effect similar to that we usually associate with liniments. Properly controlled studies to prove this point are not available but are technically possible to perform.

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There is no evidence that DMSO alters the course of any disease or is, in any sense, a miracle drug. To suggest on the basis of the evidence available to date, controlled or uncontrolled, that DMSO is a major medical advance for any serious disease, let alone a variety of such diseases, is misleading.

The work you have heard about on brain and spinal cord injury is potentially important, but I would emphasize it is also at a very early stage of clinical investigation. There are no control trials in this area, and it is premature to draw conclusions on the basis of this promising clearly early work.

This is not to deny, or be unsympathetic to, the potential of DMSO to provide symptomatic relief for patients with certain painful disorders or the possibility that a new important use may yet lie undiscovered.

The FDA is willing, indeed anxious, to approve DMSO for such uses whenever controlled trials meeting the statutory standard are available. We have worked in the past, and stand ready to work in the future, with any party in developing protocols for such trials and in expediting their review.

May I also comment that I noted in the course of the morning a number of members in this committee expressed interest in considering legislation that would revise existing drug procedures under the Food, Drug and Cosmetic Act.

I would like to point out that this administration has introduced major legislation, called the Drug Regulation Reform Act of 1979, that is currently submitted to both Houses as H.R. 4258 and S. 1045.

This legislation constitutes the most extensive revision of food and drug law in over 30 years, and proposed reforms in it include those which would streamline the approval process for new drugs and provide a mechanism for dealing with the sometimes difficult problem of developing drugs which companies perceive as having little commercial value.

This legislation reflects extensive joint efforts during the 95th Congress between the Food and Drug Administration and the House Subcommittee on Health. I would welcome the interest of your committee in that legislation.

Mr. Chairman, thank you very much. I would be delighted to answer questions.

The CHAIRMAN. Thank you, Doctor.

Doctor, what is the statute to which you refer, the statute that establishes what must be shown for a drug to be recognized by Food and Drug?

Dr. CROUT. The Food, Drug and Cosmetic Act, section 505. The standard for effectiveness is "substantial evidence" of effectiveness which means evidence derived from controlled clinical investigations conducted by experts qualified by scientific training and experience to evaluate the effectiveness of drugs.

The CHAIRMAN. Well, in the first place, the initiative must always come from the person trying to get the drug approved, is that right?

Dr. CROUT. Yes, sir.

The CHAIRMAN. You don't take any steps to try to accelerate the presentation of acceptable testimony?

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Dr. CROUT. We take steps to accelerate the handling of applications that come to us. We have a priority system for handling drugs of medical importance on a faster track than we do drugs that simply duplicate products already in the marketplace. The basic advocacy for the drug comes from the outside party, however. however.

The CHAIRMAN. This drug has been on the track for 15 years. Has it been on the slow or the fast track?

Dr. CROUT. No; the applications for DMSO have been handled in a timely way. That is not the issue. We have not had pending applications in front of us for 15 years.

The CHAIRMAN. Have you denied all that have been presented?

Dr. CROUT. No; we approved the one in 1978 for interstitial cystitis.

The CHAIRMAN. And you have not had any application for the approval of this drug since 1978?

Dr. CROUT. The scleroderma application was presented by Research Industries, also in 1978. That we turned down in 1979.

The CHAIRMAN. I believe the evidence indicates that three drug houses of national repute applied for approval to market this drug in the country, and you turned down all three of those applications. You mean those drug houses did not know how to present an application to Food and Drug to show proper evidence of value in the use of it?

Dr. CROUT. Yes, sir, that is right.

The CHAIRMAN. Had they ever had any drugs approved before?

Dr. CROUT. Oh, yes.

The CHAIRMAN. Well, they had had experience, then, in the presentation of drugs for your approval.

Dr. CROUT. Yes; but they have also had some turned down.

The CHAIRMAN. And they did not complain about your finding that they had not made any satisfactory showing of the efficacy of that drug?

Dr. CROUT. No; they did not pursue that. This occurred before I was at the Food and Drug Administration. So I cannot speak with personal knowledge of exactly what happened. No, they did not pursue those applications further.

The CHAIRMAN. Well, now, you have heard here this morning——

Dr. CROUT. Nor did they pursue their legal right to a hearing which every drug firm has.

The CHAIRMAN. You heard the testimony here of several witnesses this morning. You would not regard any of that testimony as testimony as to the efficacy of that drug in the treatment of pain and sores and sprains and that sort of thing?

Dr. CROUT. It has to be, as I point out, assembled into a scientifically designed study. There is no reason to think that the testimonies are necessarily wrong. I don't want to imply that. But there is a certain discipline that research has to go through, that every drug goes through before it gets approved, in which the studies are designed and patients are very carefully selected for the study. Right from the start one must know what is going to be measured in those patients and those measurements must be made objectively. And to the extent it is possible, the study should be blinded.

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Now, we accepted the trials done by Dr. Scherbel as designed properly at the start. The problem with those trials is they came out with the equivocal result which I mentioned to you. But sprains, bruises, and soft tissue injury have really not been subjected to the disciplined kind of clinical research that is really standard for drugs in this country.

The CHAIRMAN. Well, now, do you set up the procedures? Do you advise the applicant as to what it must show to get approval?

Dr. CROUT. We will if asked, yes.

The CHAIRMAN. Well, I am curious as to what your role is and how you regard your role. If you regard your role as that of a gatekeeper to keep anything dangerous to the public interest from passing, then you just wait until the dangerous thing comes along and you stop it.

On the other hand, it would seem to me that from all that has been said here this morning, there are a lot of people who believe that this drug has a remarkable efficacy in certain areas at least. Dr. Jacob thinks the areas may expand with knowledge and use into an extraordinary scope.

Your curiosity wasn't aroused that the 30 million people in this country that suffer pain from arthritis and maybe some fellow comes along the highway saying he has something, that might really be something that would reduce the pain of those people and say "Look here, now you have submitted evidence that has a certain amount of persuasiveness."

But, on the other hand, under the statute and our rules and regulations, we have to require that the evidence comes within a certain category and have a certain amount of probity to it. We would like you to go back and reorganize your presentation.

It is one thing for a judge to be sympathetic to a meritorious case being presented. It is another thing for a judge just to sit there and if the fellow can come up with something, all right, and if he cannot, all right. The judge assumes no responsibility.

Dr. CROUT. I understand what you are saying. Our view is exactly as you have described. I cannot speak personally for what happened during the 1960's. My suspicion is that back in the mid-sixties the atmosphere was a confrontational one.

But I do know that in the past decade it has not been. As Dr. Jacob mentioned, there has been cooperation with the FDA staff. I keep track of what is happening in DMSO and a number of other drugs, personally, as does Dr. Finkel and Dr. Gyarfas.

We don't want to give you any impression of disinterest in DMSO, of bureaucratic obstinacy or of being uncooperative. But there is a reasonable standard, a scientific burden of evidence, that drugs properly should meet if we are going to have any drug regulatory system at all. And we are asking that of DMSO, no more, no less than any other drug.

The CHAIRMAN. Well, Doctor, we understand you have a great responsibility. You might, if you acted hastily or unwisely, authorize some fellow trying to make a lot of money to put something on this great market in America, make a lot of money and maybe injure a lot of people.

And you, of course, feel a moral responsibility for permitting this to happen. I would assume that those cases would be largely limit-

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ed to those where the evidence indicated that there was a distinct possibility of danger in the use of the drug or a reaction that had serious consequences to the user.

But if there is a drug for which there was an enormous amount of prospect of good that was being pressed upon you by three drug companies who apparently thought the drug had enormous potential, in a case like that, I would think that you would be eager to see if the claims that were made could be justified. You would be looking for satisfactory proof that would square with your conscience and your judgment that that product might give relief to a lot of people and could be put on the market.

Now, the public—and I must say up to now I share the opinion—has the impression that your agency, in its desire to be careful and its desire not to let anybody be hurt, has denied perhaps a lot of people relief in fear that if they allowed the thing to be approved as it was presented, that they might be hurt by it; that yours is a negative attitude, that you don't help anybody improve his application, you don't tell them what is wrong with the application in an informal way so they can attempt to correct it and the like; that you are not eager to see the users of the country that might profit from it get the advantage of it.

You say, "It is no skin off my back," as the old saying goes, "if these folks cannot comply with the technicalities. That is the law, it is none of our responsibility. Let them get a better lawyer or somebody else. We are not running it. We are just sitting up here trying to protect the public interest."

Are you sure that there is no justification for the public or even Members of Congress having that impression of your regard of your duties? Are you sure there is no foundation for that fear?

Dr. CROUT. I am certain that we have to cope with accusations of the type you just mentioned. All I can tell you is we spend an enormous amount of time internally trying not to behave in that way.

We have meetings with industry that take up many hours. We have special check points in the course of drug development in which people come in and we work together on protocols. There is no way we can write to a firm turning down a drug without specifying the reasons for that, because the reasons can be reviewed in a hearing.

The CHAIRMAN. How long does it ordinarily take for the proof that you require to be presented?

Dr. CROUT. It obviously depends upon the drug. There is an interesting paradox. The closer the drug is to something that is already in the marketplace, the easier it is to work up. A new antibiotic that duplicates one already in the marketplace or a new tranquilizer goes through more easily than a brandnew molecule with a novel mode of action.

In the case of DMSO today there is very little that needs to be done to finish studying some of its proposed indications. It needs some small, carefully controlled trials——

The CHAIRMAN. How long do you think it would take to make a proper presentation in respect to DMSO?

Dr. CROUT. For what indication?

The CHAIRMAN. To get approval.

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Dr. CROUT. For what? It is approved for cystitis. For what indication?

The CHAIRMAN. Pardon?

Dr. CROUT. For which of the several indications?

The CHAIRMAN. Well, at least in the treatment of pain with respect to arthritis, in respect to soreness, in respect to sprains, in respect to swelling. Those are some of the questions that have been raised here today.

Dr. CROUT. Since there are no trials on that issue, controlled trials, going on now to my knowledge——

The CHAIRMAN. Pardon?

Dr. CROUT. There are no trials on that issue going on.

The CHAIRMAN. My question was, Doctor, how long do you think it would take for a proper showing if it could be made to you?

Dr. CROUT. My suspicion is a drug firm would probably take a year to do that trial.

The CHAIRMAN. A year?

Dr. CROUT. In order to get it organized, attract investigators, get it through review committees and conduct it and have the data back is probably about a 1-year venture.

The CHAIRMAN. I believe you said Dr. Scherbel had made a presentation and some of his application was approved. Do you regard him as qualified to participate in the preparation of a case?

Dr. CROUT. Absolutely, yes, sir.

The CHAIRMAN. And Dr. Jacob.

Dr. CROUT. Yes.

The CHAIRMAN. And then some drug company that is knowledgeable about it and wishes to prepare the case to present it.

Dr. CROUT. There is such a company. Research Industries is now the marketer of DMSO in this country.

The CHAIRMAN. Well, Doctor, you know I have often thought that it would make a great deal of difference—I have had in my family some tragedies, one particular tragedy. And I know how long it has taken to get interferon available. I have a dear friend now in Miami. I have talked to him. He has appealed to every place that I could refer him to. Manufacture is not going to start until July. Somebody else cannot do something for some time.

It has taken months to issue the invitation to bid. If the people that make those decisions had a wife lying there dying with cancer, I wonder if it would take them so long to come to a conclusion about how to offer the substance on a bid.

I wish sometimes that some of the people making some of these decisions had painful arthritis and it was a wretched experience every day brought to you. You would be looking a little bit more anxiously for somebody who could come up with something that could ameliorate your trouble.

Our committee would like very much to see in this particular case, with propriety—I am not asking you to do anything that is not within the law and within propriety—but if you could in a kindly way, because so many people do believe that this drug has efficacy—if you could cooperate with those who are anxious to get the data presented, and then you could give your consideration to it with all possible speed, all deliberate speed, as the Supreme Court said in a case, we would appreciate your doing so. We would

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like to see how long before you come to a full decision on this particular application.

Do you reckon you couldn't make it any shorter than a year, if the other applicants did a good job?

Dr. CROUT. Let me say that all of us in the Food and Drug Administration, like every other institution in this world, are people. We have to cope with disease in our own families. I think we are quite sensitive to some of the health issues you have mentioned.

The core of our staff are all physicians, so that they have at one time or another in their lives practiced medicine, though they are not practicing at the Food and Drug Administration. So, I think the human sensitivity you are asking for is there.

We would be delighted obviously to cooperate with the firm in advising on DMSO. I promise you that.

The CHAIRMAN. Well, we are going to advise these gentlemen here who are interested in the presentation of this application to prepare it with all deliberate speed, and to get the best person qualified to present it. We want them to make as good a showing before you as they can. We ask you to try to cut as much legal red-tape as you can, and give us as speedy a decision as you think is right in this matter.

Dr. CROUT. Fine.

The CHAIRMAN. Now, just one other question.

To what extent does the Food and Drug Administration and the National Institutes of Health cooperate or consult?

Dr. CROUT. I think fairly extensively. We are both in the Department of HEW. We both report to the Secretary. So that we have common bureaucratic bonds.

We also have a lot of informal interchange; that is, members of the NIH staff may be on our advisory committees. We may in turn consult with them.

In my testimony, when I mentioned my talking to them about the group that has promised to do a trial on scleroderma, that is an example of the informal contact that goes on back and forth.

The CHAIRMAN. Do you have an administrative setup and required personnel so that there is no undue delay in the Food and Drug Administration when proper data are presented in the decision of the case?

Dr. CROUT. Well, I think every institution probably thinks it could use more people, but I would not argue that case, today, given the overall state of the economy and general constraints on Federal spending.

We are in pretty good shape staffwise. Certainly for DMSO no staff limitations to handling an application.

The CHAIRMAN. Thank you.

I am advised by the staff that Research Industries has a DMSO application pending. It has been pending since 1978, I believe you said. What is holding up the decision of the Food and Drug Administration on that?

Dr. CROUT. That was in my testimony. Their 1978 application was on two indications—one was interstitial cystitis which we approved. The other was on scleroderma, which we turned down. There is no active application pending now, to my knowledge.

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The CHAIRMAN. Mr. Bonker.

Mr. BONKER. Thank you, Mr. Chairman.

Dr. Crout, I have not joined the chorus of criticism of FDA policies and have always resisted the temptation to co-sponsor legislation that is challenging basic decisions that you have made precisely because you are a specialized agency, and I have no means of making judgments that could contest your conclusions.

But as a legislator, I have listened to the testimony today, I have followed Dr. Jacob's career for the last 15 or 16 years, and we have not heard from unreliable witnesses today—very credible, highly regarded, professionally grounded witnesses on this particular subject.

The testimony seems compelling. If you cannot find within your statutory authority a basis of making a more positive decision, then perhaps something is wrong with the statute. Either that or the testimony that we have received today is flawed in some way.

I have looked at a copy of the Federal Food, Drug and Cosmetic Act as amended, section 505, and it seems to me that it is concerned primarily with safety and efficacy.

In section 505(e), since we seem to be talking about substantial evidence as a means of decisionmaking for your agency, it says here:

> The term "substantial evidence" means evidence consisting of adequate and well-controlled investigations including clinical investigations by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved.

You have covered that——

> * * * on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended or suggested in the labeling, proposed labeling thereof.

It appears to me that your agency has considerable discretion in making these decisions, and you can make a case either way, depending on what you perceive to be the right decision.

Now, when I go to the drug store and I look for medication, my wife may have an ailment of sorts, I know that most of the drugs that are over-the-counter are fairly marginal in their effectiveness.

If we get cough syrup or aspirin or some of the more complicated prescriptions, that maybe it will work, maybe it won't work. But obviously at some point your agency must have made a determination that there was substantial evidence in favor of that drug.

It seems to me that the testimony presented today after 15 or 16 years of notable success attested to by Dr. Jacob, and last night on "60 Minutes," and others who have appeared before this panel, that this drug must be at least comparable in its effectiveness to other drugs that are on that shelf.

Can you join me in that conclusion?

Dr. CROUT. For over-the-counter drugs, it is not always clear. That is true for some of them and not for others. We have a major review going on of all over-the-counter drugs to evaluate their safety and effectiveness.

You raise the issue of aspirin, for example. The evidence behind DMSO as an effective remedy is not nearly as great as the scientific evidence behind aspirin, that it is an effective drug. The trials are not nearly of the same quality.

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Mr. BONKER. I know the trials, but we are talking about efficacy. Since you have not authorized the use of DMSO, of course it is not going to have that same base of scientific evidence.

But nonetheless, where it has been applied, and the veterinarians who have shared their experience, fully 70 percent had used this chemical and 95 percent claimed that the drug was effective.

Again these are reputable professional witnesses. Eighty percent went on to say that it should be legalized for human use. It seems to me wherever we have had experience with DMSO, it has met that efficacy test.

I assume that it probably is competitive with other drugs that you have approved over the years. I know when I take an aspirin, 60 percent of the time it will work, maybe. It has got to be that way with most drugs because of the peculiar nature—how they apply to various people.

It just seems to me that unless there were a serious health problem involved, where it would endanger public safety, that it certainly must meet that efficacy test that has been so demonstrably presented here today.

Dr. CROUT. If I could comment. Between 1938 and 1962 there was no effectiveness standard in this country. The 1962 amendments required the Food and Drug Administration to go back and look at all the drugs approved for safety alone between 1938 and 1962.

Hardly a drug, at least for all of its claims, survived that review, in fact. About 20 percent were removed from the market because they were not effective. Almost all of the remainder had at least some ineffective claims so that the labeling had to be revised.

So, the history of the marketplace is that absent an effectiveness standard, there are a lot of drugs in the marketplace which are not effective.

I am not saying DMSO is one of those. What I am saying is that one sets up properly, the Congress set up properly—a standard, an evidentiary standard, that a drug should properly meet.

Now, there isn't any reason to lower that evidentiary standard for DMSO. It is not necessary. I think your concern should be directed in at least two ways. One may be toward us. But the other ought to be at why it has taken its advocates so much time to take their testimonial evidence and turn it into genuine science.

That is why DMSO is not on the same pathway as other drugs. It is why DMSO has become a cause celebre.

Mr. BONKER. Well, if you are referring to statutory standards—and I have looked briefly at section 505, and we seem to hinge your decision on substantial evidence——

Dr. CROUT. On controlled trials. The definition of controlled trials is actually in our regulations, not in the statute.

Mr. BONKER. OK. It must be controlled trials and not substantial evidence because I think that you can take care of any reservations you may have in the labeling that goes on the product, as it is provided for under the definition of substantial evidence.

Well, I just have to conclude that there is either an institutional bias or some kind of bureaucratic intransigence. That is not uncommon in the Federal bureaucracy, as we are beginning to discover on the Hill.

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Or that maybe the charge that you are protecting some drug firms that may view this as a marketing threat of some sort. Or last, you have a very legitimate case based on clinical or controlled evidence that you referred to today.

But I would hope, as a result of these hearings and the chairman's expressed concern, that maybe you would take a new look or review of this chemical, and see in light of the testimony and the evidence that abounds that perhaps it warrants a new review and hopefully a different decision.

Dr. CROUT. I accept that. We will do our best to cooperate.

Mr. BONKER. Thank you.

The CHAIRMAN. Ms. Oakar?

Ms. OAKAR. Thank you, Mr. Chairman, and thank you, doctor, for being with us today.

Would you submit, then, for the record the regulations for this controlled testing. Obviously they are not in the law. I don't think we want to be misled about that.

Dr. CROUT. No. The controlled trials, the words "controlled investigations" is statutory.

Ms. OAKAR. Yes, but the regulations with respect to defining that term, which we all understand are very flexible—it is not uncommon, is it, that regulations frequently do not do what we intended. I am astounded when I see HUD regulations, for example, and I am on the Subcommittee on Housing, and I say did we pass that law? Is that really what we intended? So, I think for the record we ought to get that.

Dr. CROUT. I would be delighted. Those regulations have been in effect since 1970.

Ms. OAKAR. Right. And there are no new regulations.

Dr. CROUT. No, ma'am.

Ms. OAKAR. Since 1970.

[Copy of regulations submitted are retained in committee files.]

Ms. OAKAR. Also, I asked the various doctors that we had here about their credentials and, being from Cleveland, I am very proud of Dr. Scherbel, for example, and the Cleveland Clinic's research.

He apparently has done a lot of research and has a fairly balanced view of this drug. But I think you should tell me something about these people who are on the panels that you appoint to review this research.

Dr. Jacob, for example, indicated that none of them had had actual experience with the drug. Do you try to get a balanced point of view? Do you have doctors, let's say, or nurses or people who are in research, such as the doctor we had who had a lot of experience with respect to animals?

Are any of the pro advocates on the panel along with those who might be disposed negatively? How objective are these people? What are their credentials? Have they worked with the drug experimentally, et cetera?

Dr. CROUT. On our advisory committees we try to get national experts in the particular area of the committee's work. We have 13 advisory committees that advise on prescription drugs. So, in the arthritis area, for example, our advisory committee is mainly composed of rheumatologists, physicians who either practice rheumatology or are on the faculties of medical schools.

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Many, but not all, have had some research experience. They will bring to the committee——

Ms. OAKAR. With this drug?

Dr. CROUT. No.

Ms. OAKAR. Not with this drug.

Dr. CROUT. Not necessarily with this drug, no.

Ms. OAKAR. Why wouldn't you have somebody who has worked with the drug?

Dr. CROUT. Well, it is a matter of maintaining the independence of the reviewer as compared to the advocate. I think there are certain general principles about clinical research that are well understood by research people.

Ms. OAKAR. Tell me a little more about it.

Dr. CROUT. The questions are whether the trials are controlled correctly, whether or not they really showed the effects.

Ms. OAKAR. Are they all M.D.'s?

Dr. CROUT. They are not all M.D.'s. We generally have a statistician on each committee. Sometimes we have a toxicologist.

Ms. OAKAR. With respect to the people going to do the research on this—the National Institutes of Health—who is on this committee that you are going to ask to research this that has any credential related to this drug?

Dr. CROUT. The chairman of that group, Dr. John Ward, at the University of Utah School of Medicine. I am quite certain he would be accepted as a peer by any of the previous panel that you mentioned.

The other people who will study this will be academic rheumatologists around the country.

Ms. OAKAR. So he is a teacher of medicine?

Dr. CROUT. Yes. You may ask the panel, but I would be very surprised if Dr. Scherbel and Dr. Jacob did not accept the panel as peers.

Dr. JACOB. I don't think I would accept that at all.

Ms. OAKAR. Mr. Chairman, you don't mind if I recognize Dr. Jacob?

Dr. JACOB. I think it is an insult to talk about Dr. Ward. I would like Dr. Scherbel to get up and answer some of the questions. I am not at all satisfied that the FDA is giving DMSO a fair shake.

We have proved safety and effectiveness in scleroderma. People are having their fingers amputated, and these people are sitting here and twisting the facts.

Ms. OAKAR. If you don't mind—what you are saying is the person who is going to chair this panel to again review the effectiveness you feel is personally biased?

Dr. JACOB. I have talked to him and he is anti-DMSO.

Ms. OAKAR. That is what I am getting at, Mr. Chairman. People who have done the research, who are working on a case-by-case basis—at least some individuals—feel that the people who are negatively disposed are the people you are appointing to do the research now.

You can tell me all you want about research. But you appoint at a minimum people who are objective and, second, knowledgeable, and it appears that this individual, whoever he is, doesn't have those two criteria.

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Dr. CROUT. Let me draw a distinction between two roles. One is our review committees, and the other is a committee that is set up to do clinical trials.

Now, that group has offered to conduct studies on scleroderma. I don't personally know what the individual biases of those people are.

Ms. OAKAR. Why did they offer to do it? Do they have a lot of free time?

Dr. CROUT. That group is established to evaluate remedies in the field of arthritis.

Ms. OAKAR. Could it possibly be they are negatively disposed and they want to kill this drug?

Dr. FINKEL. When our Arthritis Advisory Committee reviewed the data——

Ms. OAKAR. Can you tell me who is on your advisory committee?

Dr. FINKEL. At that time there was Dr. Evelyn Hess, Dr. Paul Plotz from the NIH, Dr. Daniel Furst, and Dr. Fernandez-Herlihy.

Ms. OAKAR. All these people are objective and knowledgeable?

Dr. FINKEL. Yes.

Ms. OAKAR. Can I ask Dr. Jacob, do you agree?

Dr. JACOB. Dr. Evelyn Hess was the chairman of the committee. She showed so little knowledge of the disease that she denied that patients who had ulcers came to amputations.

I was appalled that they would bring in an expert who didn't recognize patients with nonhealing ulcers, with scleroderma come to amputation. That to me is an insult.

Ms. OAKAR. Mr. Chairman, I am not trying to cast aspersions against anybody's reputation for the record. However, I think I have asked enough questions in this respect to get at least a negative reaction on the part of the people who are working on this on a day-to-day basis.

I think in view of that, you ought to start appointing some people who are mutually acceptable. It doesn't mean they have to be predisposed favorably. But, when you get negative reactions from individuals who have dedicated their lives and have seen results, then you can understand why the average person out there wonders what is going on.

Dr. FINKEL. May I make my point? After the advisory committee reviewed the data they felt that there may be some evidence of effectiveness. They recognized it is a very serious disease that they are dealing with, that there is no other adequate alternative therapy.

So, the advisory committee itself said let's try to set up a controlled clinical trial which will show once and for all whether this drug is effective. They were very interested in having an effective agent.

Dr. Evelyn Hess was the one who suggested that the cooperative clinics group be contacted, the one that Dr. Ward happens to be chairing right now, to see whether it would be interested in designing a protocol and in doing a study.

Ms. OAKAR. On that note—because I had that marked in your testimony, Dr. Crout, where you conclude on page 6 that DMSO may be effective. Do you mean that drugs that are approved by the FDA must be effective in every instance?

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Dr. CROUT. No. That means that they must have an effect which is demonstrably better than chance.

If for example there is a placebo effect in which there may be a response rate, let's say, of 20 percent, an active drug would have an effectiveness rate demonstrably greater than 20 percent.

One figures that out by comparing the active drug to a placebo, in the simplest form of trial. In certain other instances the new drug is compared with an already known active agent to see that they produce comparable remission rates.

But there are very few drugs that are 100 percent effective.

Ms. OAKAR. Well, that is the point. Some of the doctors testified that they would like the opportunity to deal with patients individually so that they could suit them to the proper drug to relieve the problems with arthritis.

Dr. CROUT. That is a well-established principle in therapeutics, and we accept that.

Ms. OAKAR. Because we are hearing more and more negative things about aspirin with respect to elderly people, as was testified to today—not in every instance, but in some instances.

So, I am wondering if your panel arrived at that conclusion that it may be effective, why the holdup? I just want to ask one more question. Have any drug firms intervened in FDA proceedings to oppose approval of DMSO?

Dr. JACOB. I would like Dr. Crout to comment on why indocin was approved with no control studies and DMSO was turned down from three drug companies at that same moment in time. And Dr. Finkel also.

Ms. OAKAR. Let me ask the question for you. Why don't you assume that I asked it.

Dr. CROUT. To my knowledge, indomethacin was not approved without adequate and well-controlled clinical trials.

Ms. OAKAR. Let me just conclude by saying I certainly respect the position you are in. You have the burden of defending the position of the sixties that appears to be questionable at best.

You were not around during the sixties, but I am wondering if I could ask you a personal question. Are you representing your own point of view or the view of the FDA on this?

Dr. CROUT. Both.

Ms. OAKAR. So you agree that it is not necessarily an effective drug, is that what you are saying?

Dr. CROUT. I am saying it is not proven to be so by the standards, by the scientific methods that are appropriate for drugs.

Ms. OAKAR. Thank you, Mr. Chairman. I just want to say that the American people have a hard time understanding how Premier Tito can get all kinds of drugs that our people cannot get on their deathbeds.

Really and truly, there are a lot of people out there who would like the option of at least trying something which by your admission is not toxic. Obviously the studies of the seventies contradict the studies of the sixties.

The CHAIRMAN. Thank you Ms. Oakar. Father Drinan.

Mr. DRINAN. Doctor, I commend you and your associates for carrying out the law. I fully understand what you are seeking to

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do. I am wondering whether anybody or yourself at the FDA thinks it would be useful to clarify the statutory standards.

As I have heard the evidence this morning and this afternoon, the FDA is in fact living up to the statutory standards, indicating this drug will not be approved because there is no substantial evidence of effectiveness.

You say that quite categorically, and you have the National Academy of Sciences behind you, and you have the Arthritis Foundation, a representative who will testify.

Do you people feel, in view of the controversy over this, that the Congress should think of clarifying or refining or even altering the statutory standard?

Dr. CROUT. I appreciate your comments. Let me say that I cannot speak for the administration on a legislative issue. But my suspicion is we should not.

I think it is really quite a profound thing for the Congress to begin to tinker with a standard like that, which we use every day for many, many new drugs coming by, simply because there is a controversy over one particular drug.

I think I would urge that we use some of the measures that the chairman suggested, of mutual cooperation, that we let Research Industries reappraise perhaps whether they want to take up some controlled trials for DMSO in soft tissue injury, and let the usual processes run.

My suspicion is that this is one of those items that properly doesn't deserve congressional attention, that is legislative attention.

Mr. DRINAN. I thank you, Doctor. That is my intuition, too. I am impressed, to repeat, by the Academy of Sciences and by the evidence and by the carefulness of your testing. You say quite categorically—and I really didn't hear this refuted—you say on page 8: "There is no evidence that DMSO alters the course of any disease." So I just commend you.

Dr. JACOB. That is not true.

Mr. DRINAN. And I say that clarification for the Congress of what we talked about, of that statute, would be important to me.

One last question. On page 3 you speak of a final form on this proposal now being prepared for publication. Would you tell me when that comes out and what that will finalize?

Dr. CROUT. I don't know when that will come out. That is a matter of cleaning up some paperwork on an old regulation that is now obsolete.

Mr. DRINAN. But that is not in the main run of what we are discussing here today.

Dr. CROUT. No, not really an important item at all relative to this hearing.

Mr. DRINAN. Maybe I should ask this of the next witness: Is the Arthritis Foundation bothered, I supposed, or importuned by people who want them to give some encouragement to this drug?

Dr. CROUT. They will have to comment on that themselves.

Mr. DRINAN. Thank you very much.

The CHAIRMAN. Thank you, Father.

Doctor, I just want to ask you one other thing.

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Tell us how the decision is actually made and by whom. I inferred you had advisory committees and the like. Do you make the final decision on all these drugs?

Dr. CROUT. Every drug has assigned to it a team that includes a physician, pharmacologist, a chemist, a biopharmaceutics expert, and a statistician. That team will review the application and will consult with an advisory committee, and then write a recommendation for approval or disapproval of the drug.

That will be reviewed by the division director, Dr. Gyarfas. That recommendation will in turn be made to Dr. Finkel, and Dr. Finkel has the authority to approve or disapprove new drug applications.

I engage in oversight over the whole process. So it is a collective group of people who would participate in any drug decision.

The CHAIRMAN. Well, now, Doctor, let's say Dr. Jacob and the group working with him—I am hopeful that Dr. Jacob will put together a group of knowledgeable and competent people to join him in the preparation of a new application to be presented to your agency.

Now, if they don't know enough right now as to how you think it would be best presented, with whom could they confer? Would it be with Dr. Finkel or somebody to tell them, now, this is the way we propose to set it up—does that seem to be generally all right in structure?

Dr. CROUT. Yes, sir. Research Industries has met with us on many occasions in the past. We assume they will continue to in the future. They have met with both Dr. Gyarfas and his staff and with Dr. Finkel. I am sure I can guarantee their personal attention to this.

The CHAIRMAN. Very good.

Then you will set up the proper machinery for the preparation of your material.

Dr. Jacob, I think we have made quite a lot of progress today.

Dr. JACOB. I am amazed Dr. Crout would say there is no disease altered by DMSO. It shows a complete lack of knowledge. I respect Dr. Crout and like him. He is from Oregon. But it shows a complete lack of knowledge of the literature on DMSO.

It can be stated with certainty that there are many diseases the course of which is altered by DMSO. I would like to ask a question which will be embarrassing, but I would like to ask it.

Dr. Gyarfas is in charge of the DMSO evaluations. He is on record as saying, "I am going to bury that drug once and for all." I would like Dr. Gyarfas to either deny or accept that statement before this committee under oath.

The CHAIRMAN. Very good. If you will, will you please answer the question, Doctor.

Dr. GYARFAS. I, too, have heard this accusation many times from the proponents of DMSO. I was responsible for calling an ad hoc committee to review the data on DMSO in approximately 1970 or 1971, before we established the 13 advisory committees that Dr. Crout referred to, before the mechanism of advisory committees was a well-known fact in the Bureau.

This committee we selected what we thought were the prominent men in the field of arthritis, especially in surgery. It was, as a matter of fact, a surgery advisory committee because we had no

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other committee at that time outside of an Ob-Gyn committee in the bureau.

My opening statement was that we have been wrestling with the problem of the data, or so-called data, and this was being presented to this committee to make a definitive judgment on it. No attempt to bury.

How that statement came, I don't know. I categorically deny approaching any drug with the idea of burying. I have been with the Food and Drug Administration for 17 years. I just last night reviewed my job description again.

There is nothing in there that calls for me to bury a drug. It calls for me to foster and promote and assist in the development of drugs in this country.

Thank you.

Dr. JACOB. Did Dr. Crout receive a letter from Dr. William Crepane stating that Dr. Gyarfas made this statement, and does Dr. Crout trust Dr. Crepane's veracity? Dr. William Crepane, chief of surgery at the University of Oregon Health Sciences Center overheard Dr. Gyarfas make that statement, wrote to Dr. Crout, received an answer from Dr. Crout. I would like to know whether Dr. Crout trusts Dr. Crepane's veracity.

The CHAIRMAN. Do you care to make any comment, Dr. Crout?

Dr. CROUT. I am in a position of trusting both men. I don't know how as an administrator one deals with two people who have a conflict. I don't want to see this escalate into anything other than a very unimportant segment of the whole DMSO story.

I can guarantee you that there isn't any such thing as one-person review or one-person approval in the Food and Drug Administration. I can guarantee to you that I never heard Dr. Gyarfas make such a statement, or anyone else in the Food and Drug Administration make such a statement.

I can guarantee you, as Dr. Gyarfas has, that that is not our policy and won't happen.

The CHAIRMAN. Well, you know, of course, in the courts if a judge has had any association with a case or has already formed an opinion with it, he can excuse himself from it.

But I am pleased to hear Dr. Gyarfas here today say he would, in any presentation in the future of this matter, be fair and objective and try to make an honest decision in the public interest. Is that correct, Dr. Gyarfas?

Dr. GYARFAS. Yes, sir.

The CHAIRMAN. Good. And doctor, you will certainly see to it, since the question has already been raised in this case, as far as you are able to see to it that it is done, that nobody except fair judges will be sitting on this case.

Ms. OAKAR. Mr. Chairman, I just have one quick question.

Dr. Crout, we have heard testimony this morning to suggest that FDA actually in its regulations—I am not talking about the law, but your perception of what the law should say—actually makes it very, very difficult to do the kinds of trials or experiments that you demand.

We heard Dr. Scherbel, for example, talk about the various types of physicals a patient has to get. Who is supposed to pay for this? What if the person is poor, as many elderly are, for example who

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need this kind of testing done? I am wondering, do you set up the types of regulations that actually inhibit research?

Dr. CROUT. That is a very difficult question because there clearly is a balance between wanting to get a lot of information about a drug on the one hand and on the other seeing costs escalate.

What you are describing is not really a matter of regulation. That is a matter of negotiation of an individual protocol with the firm.

We do have a high degree of flexibility in determining what particular toxicological tests need to be done, how long the trial runs, how it is designed, how many patients, and that sort of thing.

Those are the things that we will try and negotiate with the firm in the most efficient and least costly way possible for any new trials that need to be done on DMSO.

Ms. OAKAR. But you have a lot of flexibility in determining that.

Dr. CROUT. Yes.

Ms. OAKAR. Well, I think if you adhere to what the chairman is saying—and that is, if you take a certain degree of initiative in assisting to get the issues settled once and for all, then you would not put uncompromising types of regulations in the way of those who are doing the research, would you?

Dr. CROUT. No, ma'am.

Ms. OAKAR. OK. Thank you, Mr. Chairman.

The CHAIRMAN. Well, Dr. Crout, Dr. Gyarfas, and Dr. Finkel, we thank you all very much for coming here today. We are going to watch this matter with the keenest interest and hope that the public interest will be served in what shall be done.

We will call Dr. Scherbel back for a moment.

Dr. SCHERBEL. I appreciate this. I am leaving in a few minutes. I would like to make one or two comments to what Dr. Crout has said.

He indeed has a very difficult position, and for him to make some of these decisions, I just don't envy him one bit. I am sure he is doing the very best he can. This is not criticism toward him.

The study on interstitial cystitis, that was carried out and approved, was done on a very simple protocol, with historical controls. In other words, the patient was ill, the patient didn't improve spontaneously, treatment other than DMSO was ineffective. The patients then received DMSO and they improved. That was the study. Historical controls in a very simple fashion.

Investigators studying the effect of DMSO in patients with interstitial cystitis had an entirely different advisory committee than we had. Yet, it was the same drug. But the criteria, the restrictive elements that entered our study, did not occur in that study.

We had a group of FDA monitors throughout our study until the time came to present our data. Then we had a second group of FDA officials who were highly critical of the study design as well as our conclusions regarding treatment.

The last point I would like to make is that the FDA consulting committee had only one expert on scleroderma. He had never used this drug.

The study and treatment of connective tissue disease is a subspecialty of medicine. When I talked about sclerodermatous ulcers, there is not a chapter in a textbook on sclerodermatous ulcers.

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There are very few articles written about sclerodermatous ulcers. The FDA officials and members of the consulting committee are not authorities on treatment of sclerodermatous ulcers.

Now, out of all these patients—and I was able to get these patients from a seven- or eight-State area—we had just a few who would fit this very unique criteria of having persistent symmetrical ulcers on both hands. This is very rare.

For those of you who don't understand scleroderma, patients might have one ulcer on one finger, one on another which may last 3 months, while another lasts 2 weeks.

When a study group starts putting patients like this together, they better have 200 patients, and not 19.

The result will be DMSO has been a therapeutic failure, it does nothing for these ulcers, and therefore we cannot approve it.

Thank you.

The CHAIRMAN. Doctor, do you make the point that on this panel that makes the original recommendation there are not enough people who know something about arthritis and those kinds of diseases?

Dr. SCHERBEL. No; I didn't mean to state that. That is not what I meant. I was trying to say this is a very difficult problem because the drug is unique. There is no drug that works like this.

When we submitted our material, this was again unique because nobody has talked about a group of sclerodermous patients with bad ulcers.

Now, in the group I was referring to, when I submitted my report, I presented patients with ulcers that were persistently present. Ulcers were not appearing and disappearing. I presented patients with ulcers that were constantly present for 1 year or longer.

An investigator does not need a large number of patients to determine effectiveness if these ulcers begin to heal. At the end of the study these patients were not having a serious problem with ulcers.

In my mind treatment with DMSO was very effective. It was very surprising to me when we went to FDA and were told DMSO effectiveness was questionable. I have talked to very competent clinical pharmacologists in this country who tell me that there are many ways of determining if a drug is effective. One does not have to have the type of study that FDA insists upon we have with this drug to prove efficacy.

There are many ways of providing an effectiveness with a drug. But if one insists on a double blind study this drug will never become available. The investigator knows who is getting the drug, and who is not.

The dose of the drug varies so greatly. It is difficult to determine beforehand who is going to tolerate 30 percent concentration, there are many of my patients I have increased from 30 percent to 50 percent to 70 percent rapidly, and others very slowly.

You have to individualize these patients. So, if one says, well, the drug doesn't work because 30 percent didn't work, I take great issue with this. The authorites who are evaluating DMSO are not the investigators who have used this drug for 10 or 15 years to learn these little idiosyncracies.

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That is why I don't think this drug will ever be approved. A strict protocol with double blind studies, are demanded.

The CHAIRMAN. Dr. Crout, would you regard the testimony of Dr. Scherbel as relevant to the decision of this question as to whether this drug should be approved or not for limited use?

Dr. CROUT. As relevant, yes, sir. He has said that before our advisory committee and before our agency before. I regard Dr. Scherbel personally and professionally as an outstanding person.

The CHAIRMAN. So that would be relevant to you, his experience would be relevant to be included in this.

Would you regard Dr. Paul—he spoke of his experience this morning with a certain use of the drug, of the substance, in Toronto, in the hospital.

Dr. CROUT. I am not familiar with his work. I don't believe that bore on our decision on scleroderma. Dr. Scherbel conducted a trial on scleroderma which was the subject of a careful review for a whole day before our advisory committee.

The CHAIRMAN. What about Dr. Reedy? He was the physician for a professional football team. He used it over a period of years. And then Mr. Jones was the quarterback on a professional football team, and he spoke about his own experience with it. Would testimony like that be relevant?

Dr. CROUT. Not helpful, no, sir; not unless it is put into a scientific study and controlled and there is some comparative look at other drugs, or at different concentrations, or under other conditions to let you know that the effects observed are drug related.

The CHAIRMAN. Well, the tribunal that makes the first recommendation, is it the existing tribunal or a new one to be appointed by you?

Dr. CROUT. We give problems like this to standing advisory committees. The members of that turn over in part each year, because people serve 3- or 4-year terms. So any problem with DMSO would come back to the arthritis advisory committee. By the time it did we assume there would be some new members, but also some of the former members would still be there.

The CHAIRMAN. I would think, Dr. Scherbel, when I see the high regard Dr. Crout has for you, when you find out this application is prepared or being presented, and you know who the advisory committee is, or who the other committee is, if you find you don't think there is anybody on there really qualified to make this decision, I would think you would be permitted to go to Dr. Crout and tell him so, and let him consider your comments.

Dr. SCHERBEL. I don't think it is Dr. Crout or the advisory committee. I don't think this is the problem. I think the problem is we are dealing with an unusual type of drug and an unusual condition. And there is nobody, unless he has worked with this drug this period of time, who could speak with any authority about DMSO drug action.

Here is our problem.

I don't think——

The CHAIRMAN. If you follow my suggestion and my earnest plea for you, according to the sort of understanding we arrived at here this afternoon, that you are going to get fair if not sympathetic understanding and consideration when this new application is pre-

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sented, then you keep a copy of that record. And we will all have a chance to look at it later on if necessary to see whether it looks like a fair record or presentation, and others can judge as to whether the Food and Drug Administration fairly appraised and evaluated the data that was presented in that record.

Dr. JACOB. There will be a lot of fingers amputated in the next couple of years while we play this ridiculous game.

The CHAIRMAN. Dr. Crout and I have agreed on 1 year at the outside. He is going to try to do that even quicker, if possible.

Dr. CROUT. Those are estimates of how long it would take to conduct the trial. We are not conducting the trial. How it works out in the end is going to be dependent on the energy and the discipline brought by those conducting the trials.

The CHAIRMAN. Well, of course it depends on how soon the case might be presented to you. You would obviously have to have a reasonable time after it is presented to you for consideration of it.

Would you think within a year at the outside that the conditions could be met if they were capable of being met: that is to say time enough would elapse to where these controlled studies could have been made?

Dr. CROUT. For sprains and bruises, because that is a common problem, it is easy to recruit patients and should go very quickly. As I pointed out, a scleroderma trial is likely to take longer for the reasons that Dr. Scherbel mentioned. That is an uncommon disease and there simply are not——

The CHAIRMAN. Well, what if they are incapable of discovering within a year?

Dr. CROUT. The problem is to get it organized and get the people on a protocol and to recruit patients. Remember that patients with scleroderma, many of the patients, can participate in that trial and will get DMSO by virtue of their participation. So at least some of the population in the country gets treated as a result of participating in the trial.

That is a recruitment incentive to them.

The CHAIRMAN. Doctor, I have found when we want to do something very badly, we can do it a lot quicker than we can if we don't want to push it too fast. We are dealing with something here that may mean a great deal to the public interest, to a lot of people, millions of people. And let's not delay 1 day.

I know when my dear wife was diagnosed as having cancer, when they wanted to give her chemotherapy, the doctor said "We will start in the morning." I said, "No, let's start this evening."

You have heard the old story about the tree that took 500 years to grow. The question was when were they going to plant it. One fellow said, "It takes 500 years to grow." And the other fellow said, "Well, then let's plant it this afternoon, by all means."

So let's try to see if we cannot make a record, scientifically sound and reasonable at the same time that there won't be any inference whatsoever that it will be properly derived, so there would not be unusual delay with respect to it.

I want to ask you if I may that you cooperate, Dr. Crout, in any way you can toward that end.

Dr. CROUT. Yes, sir.

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The CHAIRMAN. Thank you very much. Dr. Scherbel, we have some more work for you. I think they are going to have you busy preparing this new application. So you better start collecting data.

Ms. OAKAR. Mr. Chairman, before Dr. Scherbel leaves, I do think that Dr. Crout ought to answer the one specific point that he makes with respect to this particular disease, and that is I think he is saying you cannot possibly evaluate it if you have not worked with it over a period of time. Is that not correct? Isn't that pretty much what you said?

Dr. SCHERBEL. Say it again, please.

Ms. OAKAR. That you cannot possibly evaluate the effects of DMSO accurately on scleroderma if you have not been working on a day-to-day basis with these people, because it is such a rare type of disease.

Dr. SCHERBEL. The rarity was to get the type of patient where I think we could prove simply effectiveness of treatment. The plan was to find patients with bilateral fingertip ulcers persistently present. The ulcers were not intermittent. These patients had ulcers that were present for over a year.

As they were treated, one hand that was treated improved very nicely. Within 3 months there was a marked change. Within 6 months the other hand began to improve, which we expected. We said it was a cross-over effect of the drug. But our advisory committee said no, this is spontaneous improvement, these ulcers are beginning to heal.

Well, after 6 months we treated both hands, which was the protocol. And at the end of 1 year these patients had no ulcers.

Some patients will not stop DMSO treatment. They believe ulcers stay better healed with persistent DMSO treatment.

This part of the study may be considered a historical control. To me the explanation is simple enough. Something happened during treatment which is very unlikely to be spontaneous improvement.

Ms. OAKAR. Dr. Crout, can you guarantee this committee that none of the people who viewed DMSO negatively in the past will be on the evaluation committee in the future so that we assure objectivity?

Dr. CROUT. No; I won't guarantee that. I don't think that is the way you guarantee objectivity. You cannot load the committee. People on this committee did not, as far as I know—and I would be pleased if Dr. Scherbel could tell us if he feels differently—have any personal biases. There were only scientific reasons for a different point of view.

Ms. OAKAR. All I am asking you is yes or no. Will you guarantee to this committee that no one who was on the previous panel that evaluated DMSO, whether they were pro or con, will be on the committee again.

Dr. CROUT. No, I won't guarantee that.

Ms. OAKAR. Then, Mr. Chairman, I don't see how we can arrive at any other conclusion, if you, Dr. Crout, are not willing to have a clean slate to consider this issue. Because if you put the same predisposed people on the panel they are going to come to the same result. You don't have to be a sophisticated research technician to know that.

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Dr. CROUT. I would have to disagree. We have many examples of advisory committees having changed their views, being persuaded by evidence. I think the one way to taint a regulatory decision so that it doesn't have credibility is to in some positive way load up the advisory group in a certain direction.

Ms. OAKAR. Don't twist what I am asking you to do, please. I am not suggesting that you load up any kind of investigative committee. I am not suggesting that in the slightest. What I am suggesting is that you put on this committee a group of people who have the appearance and perception of being objective, because obviously there are those people who will work with this issue who are not objective.

Dr. CROUT. And I am countering by saying to my knowledge there was no complaint that those people were not objective.

Ms. OAKAR. You just heard some.

Dr. CROUT. There may be a disagreement between those people and Dr. Scherbel.

Ms. OAKAR. Then you are not willing to make that guarantee. I don't want to prolong this.

Dr. CROUT. We have had a fair amount of experience with sending things to committees. I am simply suggesting we all be sensitive to the value of continuity of process, because——

Ms. OAKAR. No, I'm sorry, I don't agree with that. But that's all right. You have answered the question for the record. That is all I wanted to know. Thank you.

The CHAIRMAN. Thank you very much.

All right. Our next witness is Mr. Charles C. Bennett, vice president of public and professional education, the Arthritis Foundation, Atlanta, Ga.

We would welcome whatever statement you would like to make. If you have a written statement we would like to put it in the record and let you summarize it orally, if you would like to do so.

STATEMENT OF CHARLES C. BENNETT, VICE PRESIDENT, PUBLIC AND PROFESSIONAL EDUCATION, ARTHRITIS FOUNDATION, ATLANTA, GA.

Mr. BENNETT. Thank you, Mr. Chairman. I appreciate the invitation to testify.

I think the major constituency we are all concerned with has not had quite enough spotlight here today—arthritis sufferers and victims.

I would like briefly to highlight the magnitude of the problem.

There are 31.6 million people in the country with arthritis to some serious degree, which comes to 1 in 7 people. Incidentally, the prevelance rate over 65 is 1 in 2. Of that 31.6 million total, an estimated 6.5 million have rheumatoid arthritis. Of the major forms, this is the most serious, most potentially disabling, and the most painful. Only a small percentage of that 6.5 million—but still a percentage that runs close to 1 million people—have the disease in such a serious and unrelenting form that even conventional therapy doesn't really keep it under control. It leaves them in unnecessary pain and rather rapidly progressing to deformities. It makes them totally desperate, which is quite understandable. And

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they will try literally anything to find relief, regardless of risk, regardless of cost.

One thing that has not come out at this meeting today so far is something I think is rather important in terms of perspective.

This group of people, along with a lot of other arthritis sufferers, are really sitting ducks for any kind of unproven remedy.

I staff the Arthritis Foundation's Committee on Unproven Remedies. Even now, sitting here all day I consider DMSO an unproven remedy for arthritis. It happens that the arthritis victims I speak of make up a hard core group in the United States who have been going for the past 8 years or so to clinics in Mexico, one clinic in particular, to get DMSO. They supposedly get intravenous DMSO while they are there, and they bring back big supplies of dose-yourself medication when they return.

It is interesting that when they come back, by and large their testimony is that they have experienced wonderful relief, dramatic relief. And so they become DMSO disciples. The switch is that investigation so far seems to indicate they don't get DMSO at all; they are getting other medication, most of it medication which is available and conventionally used in this country, but would not normally be prescribed and administered in the same way. When arthritis patients bring medication back from Mexico, they usually take it without proper supervision.

So here we have, on top of the kind of wonder drug thing that has grown up around DMSO over the years, a large group of arthritis sufferers who are convinced, totally convinced, that this is a wonderful agent for their arthritis. Their experience makes them doubly puzzled, to put it mildly, as to why the FDA, the authorities, don't release it for use in this country. They are attracted to Mexico in the first place because it is a banned drug in the United States. And I think they become convinced that there is some kind of a conspiracy in this country to withhold it.

We have been hearing intimations of that as we sit here today.

I think it is important for the committee to consider the distortions in the reputation of DMSO—its public reputation—that results from this particular Mexican clinic operation.

The Arthritis Foundation's role in the DMSO controversy is the same as it is with all proposed remedies. That is being "for" the patient first and foremost, a patient advocacy role. Our job, as these things come up, is to determine the facts as best we can and provide guidance to help people make the wisest health decisions for themselves.

In the past 8 years, my department has put out eight advisories on DMSO, each of them generally triggered by some kind of publicity, something that has brought DMSO into the news.

So you see our concern here first and foremost is with consumer protection. It is a health education problem for us.

I would like to think that the Arthritis Foundation is and has been neutral about all this, that we don't take sides. We have concurred with the position of the scientific community generally, including the ad hoc committee we have heard about today.

We did at one time when the Florida Legislature was considering legalizing DMSO in that State, make a statement opposing that particular procedure in particular. The idea that a State should

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take that type of health concern into its own hands was decided by authorities at the Arthritis Foundation as something we should take a position against. That may seem to a number of people to put the Arthritis Foundation in a position of being against DMSO, rather than pro or rather than neutral.

There are many people who think we are against it. It does not make you popular with arthritis sufferers to tell them that what they believe may provide them some relief is something that is probably a ripoff and that they should stay away. They are desperate, and they generally disregard such advice, and they don't like the people who have told them that maybe they are getting hooked into something.

The Arthritis Foundation is not against DMSO. We would be delighted if it were established by appropriate scientific procedures to be effective. I don't think the safety question seems to be a major one. That is pretty clear. But the question of effectiveness for arthritis, particularly for inflammatory arthritis, particularly for chronic arthritis, is not clearly resolved. The question of finding an agent that will deal with the pain problem in a disease that goes on and/or involves a search for something that works not just for a short-term overnight basis, but in long-term chronic use.

That is another aspect we have not heard much about today. But it has to be a concern to rheumatologists and to the people in the scientific community who are trying to measure the relative values of agents of this kind.

The question concerning DMSO, of course, has been asked over and over again: Why is it taking so long? There has been an awful lot of looking for someone to blame, of seeking scapegoats, of recriminations. We have heard a lot of it today. I think this contributes to an atmosphere that makes it very difficult to establish scientific truth. Truth is what the Arthritis Foundation is primarily interested in seeing come out of all this.

Somebody at the very outset this morning used a phrase that clicked with me. "Let's break the logjam." We couldn't agree more that that is the most important thing to do. But not, in my view, with compromise of accepted scientific standards.

If it is proper and appropriate and accepted to modify those standards in this particular case, well, and good.

I would like to end with a plea that the committee ask the right question. I sense that it has already been decided by everybody that DMSO does work, and that the question being asked is, how do we get this wonderful drug which works so beautifully approved for use? I would like to propose, in conclusion, modification of that question: How can it be established with certainty the degree to which DMSO does or does not work for arthritis? To my knowledge, that has not yet been satisfactorily resolved by the scientific method.

Thank you.

[The prepared statement of Mr. Bennett follows, as well as his supplementary statement, submitted for the record on March 27, 1980.]

PREPARED STATEMENT BY CHARLES C. BENNETT

My name is Charles C. Bennett. I have been on the national office staff of the Arthritis Foundation for 13 years, at one period as Director of Public Relations, and

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currently as Vice President for Public and Professional Education. One of my concerns has been and is to try to keep track of drugs and other treatment methods proposed for arthritis, and to provide information services in this area to the Foundation's chapters, to the news media, to arthritis sufferers, and to the public in general. I also staff the Arthritis Foundation's Committee on Unproven Remedies.

I appreciate the invitation to testify concerning DMSO, a drug which appears at this time to fit in the arthritis "unproven remedy" category.

DMSO obviously is a "problem" drug to many people in different ways. I would like to review for you: (1) the magnitude of the overall arthritis problem and where DMSO fits in; (2) how the drug is a problem to the Arthritis Foundation; (3) the Foundation's position concerning it; and (4) some conclusions.

There are 31.6 million people with arthritis in the United States, according to a 1976 survey by the National Center for Health Statistics. The total population at the time was 211 million, which meant the prevalence rate was one in seven people.

It also means that approximately one in seven of the constituents of each member of the Committee has arthritis to some degree.

Of the 31.6 million, 10.6 million are over 65, for a prevalence rate of one in two.

Also out of the national total, an estimated 6.5 million have rheumatoid arthritis. Of the major kinds of arthritis, this is the one which causes the most pain and potential disability. A small percentage—but it adds up to nearly one million—of these rheumatoid arthritis victims have the disease in such a serious and unrelenting form that even the best of treatment fails to keep it under control. Their pain can be agonizing and relentless. Disabilities can develop rapidly. These people become desperate and willing to try anything for relief, at any risk, at any cost. This is totally understandable.

For the past eight years or so, border arthritis clinics in Mexico—particularly one in Piedras Negras—have had enormous success in luring such sufferers to receive what is alleged to be DMSO, a drug "banned" in the United States. Patients stay for two or three days to get intravenously what is advertised as DMSO, and buy large take-home dose-yourself supplies of pills, also supposedly DMSO.

They return from Mexico with glowing reports of severe disabilities and pain disappearing overnight, and consistently good improvement for a time afterward. This kind of testimonial helps to recruit planeloads of arthritis sufferers from throughout the U.S. to make the pilgrimage. According to report, treatment fees and travel together cost a Florida woman $1,400 each time she visited the clinic.

They are getting help for their arthritis, but the switch here is that it's not DMSO that's doing it. Investigation has shown that patients actually get other medication which is generally available in the United States, but prescribed with caution because of risks.

There's no telling how many thousands of arthritis sufferers have gone this Mexican route and are not DMSO disciples. To what extent was the false public image of DMSO a factor influencing the action of the legislative bodies in Florida to legalize DMSO within the state?

From its beginnings back in the early 1960s when DMSO was first acclaimed as a "wonder drug" for arthritis, the scientific issues concerning its effectiveness and safety have been clouded by emotionalism.

Add DMSO's Mexican image today, and it's no wonder there are pressures from people who believe there must be some nefarious reason that the drug hasn't been released by the FDA. I submit that if the Committee seeks to sort out scientific truth concerning the merits of DMSO, it must appreciate the distortions that evolve from what I have just described.

The Arthritis Foundation's first allegiance in matters of arthritis remedies is to the arthritis patient, or victim. Patient advocacy is a key role for us. Arthritis sufferers turn to the Foundation—especially to its chapters—for answers to questions about remedies. We encourage that.

We view it as our obligation to determine facts and provide them as guidance in helping people with arthritis to make wise decisions about their health. Since 1973, my office at the Foundation has issued eight advisories on DMSO to our chapters, constituting updates, status reports, and guidance for handling public inquiries.

So for the Foundation, the DMSO controversy has been and is first of all a consumer protection/public health education problem.

To the extent that determining and reporting facts is neutral, then the Arthritis Foundation's position is neutral. We have not sought to "take sides"—I don't think that would be appropriate for us.

But the Foundation did go on record in 1977 as disapproving legislation to permit use of DMSO by individual states. And we did indicate that we accepted the conclusions of the Ad Hoc Committee on Dimethyl Sulfoxide of the National Acade-

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my of Sciences-National Research Council. Some might not consider those positions to be neutral.

There are people who think the Arthritis Foundation is "against" DMSO. That's not so at all. We would be delighted if it proved through a full course of controlled clinical testing to be a truly effective remedy for arthritis.

But we are against promotion of DMSO or any other remedy that makes claims for which there is not yet acceptable scientific proof. We are against promotion that dangles what may be false or unrealistic hope before arthritis sufferers, who are already deluded and bilked and led down the garden path in so many other ways.

The crux of the DMSO impasse seems to be time. Why has it taken so very long to resolve the doubts about it?

This repeated question has been accompanied by fault finding and a search for scapegoats. This atmosphere only inhibits reasonable approaches to solutions.

If some way could be found to wipe the slate clean of the disputes of the past, then perhaps the new question can be posed: What would it take—starting now, and without sacrifice of proper scientific standards, and without bias—to determine DMSO's value as an arthritis remedy, good, bad or indifferent, and lay the matter to rest?

I do not have an answer. But I believe, oversimplified as it is, that this is the critical question that should be addressed.

Supplementary Statement by Charles C. Bennett

I respectfully submit this statement, with the request that it be made part of the record, to supplement both the prepared statement and oral testimony which I presented on March 24, 1980 at the hearings on DMSO held by the Committee.

My purpose is: (1) to propose a possible solution to the immediate DMSO approval impasse; and (2) to bear witness in defense of the scientific integrity of certain rheumatologists which was impugned at the hearing on March 24.

PROPOSAL

Speaking for the Arthritis Foundation, I propose that appropriate sponsors (Research Industries Corp., or other interested party) be encouraged to submit to the FDA a New Drug Application for release of DMSO as a prescriptive topical analgesic for such condition as: pain in joints, muscles, ligaments, tendons and other tissues due to strains, sprains, certain types of traumatic injuries incurred in sports and/or accidents, etc.; osteoarthritis (degenerative joint disease); bursitis, tendinitis, and other poorly defined disorders of the musculoskeletal system in which diagnosis has eliminated serious systemic disease.

It appears that with such limited use clearly defined, it might be possible to have DMSO approved and available as a palliative remedy within a short time; while clinical studies, which predictably will take much longer, are continued to establish the efficacy of the drug for major and critical chronic conditions such as rheumatoid arthritis, scleroderma, and some of the other rheumatic diseases for which it has been proposed.

The FDA's positive reaction to this proposal is noted below.

I submit the following as the Foundation's argument for such a course.

(1) It seems clear that the side effects of DMSO are so mild and so few in the vast majority of cases that its short-term safety is not of significant concern and is not involved in withholding of approval. Furthermore, it may be that sufficient scientific testing has already been carried out providing adequate evidence of safety which would not have to be repeated and which could be cited in an NDA.

(2) There seems to be virtual 100 percent agreement among the experts that DMSO appears to be effective in providing short-term relief of pain. If valid tests acceptable by stringent standards have not yet provided conclusive evidence of this, it might not take an inordinate amount of time or money to produce such evidence.

What I am suggesting would, if accepted, make the drug widely available for a multitude of ailments of considerable consequence to the public; though not yet for major inflammatory arthritis and other rheumatic diseases. It seems to me that the proponents of DMSO have not done their cause any favors by making a vituperative issue of its rejection for an uncommon and highly unusual disease, scleroderma, while not even applying for its approval in treating a variety of lesser conditions about which there is less scientific doubt and little controversy.

The Arthritis Foundation has solicited unofficial reaction to this proposal by authorities at the FDA. They have responded by saying they consider it reasonable, and already intended to solicit such an NDA. But of course until a specific application is received and the clinical trials that are used to support it have been reviewed, no promise can be made.

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For the Arthritis Foundation, I recommend this proposal for your consideration.

OBJECTION

I feel it necessary to state for the record strong objection to certain comments made during the Committee's hearing on March 24. The professional integrity of two rheumatologists by name and others by inference was attacked by Dr. Stanley Jacob. This was permitted to go unchallenged and was even used as the basis for a suggestion by a member of the Committee that the FDA should drop certain individuals from its Arthritis Advisory Committee for bias.

Dr. Jacob himself is admittedly and demonstratively biased for DMSO, which should make him the least qualified person to judge the bias of others who are not in agreement with him on the subject. As the record should show, he identified Dr. John R. Ward and Dr. Evelyn V. Hess as being totally "against" DMSO, and therefore unqualified to serve on the FDA's advisory committee or otherwise evaluate the drug. By extension, it was implied that other members of the committee who may have "voted" against approval of DMSO for scleroderma were also guilty of bias that should disqualify them from serving on the committee.

This comes through to me as saying, in effect, that being "for" DMSO is being a Good Guy, whereas voting against it in the jury room is criminal.

No one challenged or contradicted these accusations by Dr. Jacob. Does the Committee not believe it possible for scientists of repute to put aside whatever their personal experiences might have been with a drug and to evaluate evidence placed before them without prejudice, and pass fair judgement? I am not aware of a shred of evidence showing that the FDA advisors acted on any basis other than their best scientific judgment.

The atmosphere in the hearing room was that FDA advisors and staff were convicted of bias simply because other people did not agree with their judgment. I submit that many of these people were not and are not in possession of the factual scientific evidence on which the judgment was based.

Dr. John R. Ward for a number of years has been director of a national "cooperating clinics" program in which a variety of drugs and other remedies for arthritis have been submitted to controlled trials at a consortium of centers, with the information collected in a central data bank. For many years this has been the largest single testing mechanism for arthritis remedies. The project has been supported on an ongoing basis by the federal government, and is conducted completely independent of the pharmaceutical industry.

The position of director is one of considerable prestige and Dr. Ward has to be one of the most knowledgeable people in the country about what it takes to prove or disprove the scientific merits of an arthritis drug. He is a scientist in the truest sense, for all that implies about objectivity. If he is, as Dr. Jacob stated, "against" DMSO, it is on the basis of some scientific knowledge he has rather than because of some personal prejudice. Dr. Jacob's accusations and inferences were supported and uncalled for.

The same is true of his comments concerning Dr. Hess. The Arthritis Foundation knows Dr. Hess also to be a totally reputable scientist whose very training, like that of all scientists, included conscious drilling in the elimination of bias of all kinds in the consideration of scientific evidence. She is a highly respected teacher, and researcher in rheumatology, and a clinician with serious concern for the welfare of her own patients with arthritis.

I believe that the Select Committee on Aging owes these two individuals an apology for permitting the attacks on their integrity to go on the record without challenge; and I appreciate this opportunity to come to their defense.

[News Release]

ARTHRITIS FOUNDATION,
Atlanta, Ga., March 30, 1980.

FOUNDATION SEEKS APPROVAL FOR CONTROVERSIAL ARTHRITIS DRUG

[NOTE: STATEMENT ATTACHED]

ATLANTA, March 30.—While debunking "wonder drug" claims for a controversial arthritis remedy, the Arthritis Foundation has for the first time endorsed it, for limited use as a pain-reliever.

Text of a proposal for achieving approval of DMSO (dimethyl sulfoxide) by the FDA was released here today by the Foundation. It was addressed to a committee of Congress which held hearings on the drug in Washington last Monday (March 24).

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[NOTE TO EDITOR: Background information on DMSO is given at end of this release.]

Public clamor about the supposed cureall was revived by the hearings and a report on the top-rated "60 Minutes" TV program on March 23.

"DMSO has been acclaimed as a 'miracle drug' for arthritis for a number of years, but it's no such thing," according to Charles C. Bennett, vice president for education for the Arthritis Foundation which is headquartered in Atlanta.

It has had a stormy history, he said, with emotionalism by DMSO proponents clouding the scientific issues. "Widely publicized but unscientific testimonials and phony Mexican DMSO clinics have combined to give the drug a false and exaggerated reputation," Bennett explained.

"DMSO is by no means a worthless drug," he said. "It appears to work as a local analgesic and therefore might be useful in a host of conditions causing pain. But there is no scientific proof that it reduces swelling and inflammation (which are of such critical importance in rheumatoid arthritis, for example), or that it changes the underlying course of any connective tissue disease."

According to Bennett, rejecting what he calls "unfair attacks" on the FDA for holding up approval of DMSO, that agency does not now have on file any application to release it for limited analgesic use.

The most recent applications have been for approval of DMSO for treating a bladder condition called interstitial cystitis, which was granted; and for scleroderma, a serious but uncommon rheumatic disorder. The latter was turned down because the trials did not conclusively prove its effectiveness.

The Arthritis Foundation is hoping to break the approval logjam by stimulating the necessary testing and application to the FDA to get DMSO ok'd for lesser pain problems—without waiting for time-consuming trials needed to clear up questions about the drug's usefulness for serious systemic conditions, Bennett said.

He referred to testimony last Monday by the FDA's Bureau of Drugs director, Dr. J. Richard Crout: "There is much testimonial evidence to suggest that DMSO relieves pain after local application to injured or inflamed tissues. This is an effect similar to that we usually associate with liniments. Properly controlled studies to prove this point are not available but are technically possible to perform."

The Foundation has a second aim in announcing this apparent change in its position, Bennett said. That is to correct misleading ideas arthritis sufferers have about what DMSO can and can't do for their disease.

"Many people have thought the Arthritis Foundation is 'against' DMSO. This is not true at all. What we are against is misrepresentation of facts about DMSO and especially about the Mexican DMSO clinic deception," he said.

There are more than 31 million people in the United States with arthritis, many of them in such truly terrible and unrelenting pain that they will try anything at any cost and any risk, he explained. Clinics in Mexico lure them with promise of relief with DMSO, a drug "banned" in this country.

"For about eight years arthritis victims have been going to Mexico by the thousands, getting treatment on the spot and bringing big supplies of medication back home for self-dosage, which they believe to be DMSO," Bennett continued. "They say they get wonderful relief and even recover from disabilities, and they become DMSO disciples.

"The truth is, this relief isn't due to DMSO at all. Investigation has shown that the arthritis patients don't get that drug. They are lied to.

"Instead they get phenylbutazone, steroids and tranquilizers, which are available in the United States but are risky and should be taken under close medical supervision. In some cases patients have brought back dipyrone, a drug capable of causing fatal complications."

So the Arthritis Foundation says to people who have rheumatoid or other inflammatory arthritis that DMSO isn't the drug for them. They need more than pain relief; they need to have the inflammation suppressed, something even aspirin in proper dosage can do, but DMSO can't.

BACKGROUND ON DMSO

Dimethyl sulfoxide (DMSO) is a well-known industrial solvent used for many years.

In 1963 its manufacturer, Crown-Zellerbach Corporation, patented DMSO as a drug, and the University of Oregon Medical School issued press releases on reports by Dr. Stanley Jacob of its use in treating musculo-skeletal diseases, including arthritis. Although sometimes administered by injection, it is most commonly applied to the skin, which it penetrates deeply and rapidly.

A great deal of publicity followed, in which DMSO was hailed as a new "wonder drug" for a variety of diseases. The FDA at first permitted limited testing, during

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which thousands of patients received it. But in 1965 further testing was banned as a precaution, following reports of eye damage in test animals given the drug.

In 1968, the FDA again permitted clinical testing, under limited conditions, which have since been relaxed. DMSO continued over the years to be the subject of often bitter public controversy, fueled in part by the Mexican clinic connection and the false image of DMSO it caused. The target of critics was the FDA.

In 1972 the FDA asked the National Academy of Sciences to review all available information on the effectiveness and toxicity of DMSO and come up with an independent judgment on these concerns. A committee of experts was appointed which studied 1,200 papers on DMSO and 193 volumes of reports in the process of review and preparation of its comprehensive medical and scientific evaluation.

In sum, the Academy concluded that there was still inadequate scientific evidence of effectiveness of DMSO for the treatment of any disease; and although it appeared to be safe for short-term use, all potential for toxicity had not been eliminated by studies to date. These conclusions were in agreement with the position of the FDA, and were accepted by the Arthritis Foundation.

A noteworthy fact about DMSO: No matter how administered, and even when only a small amount is used by a patient, it always results in an oyster-like taste in the mouth and a strong garlicy breath odor. This makes normal controlled trial testing under "blind" conditions virtually impossible, because the odor is a giveaway as to who gets the drug and who doesn't.

The CHAIRMAN. Mr. Bennett, you personally have not seen evidence of the efficacy of this drug in respect to arthritis.

Mr. BENNETT. No, sir, I have not. I have seen many times, as we all did on "60 Minutes" last night, the testimony that individual patients provide, which I do not discount.

The CHAIRMAN. Have you known of instances where it has been applied to patients who have arthritis?

Mr. BENNETT. Not people I know personally, but second-hand I have heard about it, yes.

The CHAIRMAN. You have never actually seen a patient who had a complaint, pain, swelling, and the like, actually apply this substance and then see what effect it had?

Mr. BENNETT. No, sir, I have not.

The CHAIRMAN. You simply base your decision or your opinion upon your presumption that the Food and Drug Administration acted fairly and objectively in denying the approval of the drug.

Mr. BENNETT. Well, yes. I think I should qualify it a little bit by saying this: We accept the opinions of the scientific community, primarily the rheumatologists, the experts in the field. They serve as our advisers; they are the people who deal mostly with arthritis patients. They are the ones who conduct the key research.

They, incidentally, are the people that serve on the FDA's arthritis advisory panel. And there are many more experts in addition to those that serve on the panel and to those in this room, experts whose opinions I think might not necessarily agree with everything we have heard here today and that might be of value for the committee to hear.

The CHAIRMAN. Did some of those people actually see the application of the substance to pain and swelling and sprain, strain?

Mr. BENNETT. Yes. For example, I believe Dr. Baum has here on my right.

The CHAIRMAN. Dr. Baum, he will be the next witness.

I have what appears to be Dr. Baum's statement, at the conclusion of which he says it might be of some use as an analgesic agent in a kind of arthritis called ankylosing spondylitis.

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In acute traumatic injuries, sprains, and other such conditions in which early analgesic therapy is required, I think that DMSO would have an important role in therapy, because of the rapidity of its action and the simplicity of its application.

I would construe that as a rather favorable comment from Dr. Baum.

Mr. BENNETT. Did I imply something that would make me be in disagreement with that? Because if so, I did not intend to.

The CHAIRMAN. Any questions?

Ms. OAKAR. Thank you, I do have a few questions.

First of all, thank you for being here and being so patient in staying.

Mr. Bennett, you mentioned initially that it seems somewhat voguish for people to lure people to Mexico for DMSO treatments and call this a wonder drug. I hope I am not misquoting you. None of the people we heard from this morning and this afternoon practice in Mexico, that I know of.

Dr. Scherbel, from my city of Cleveland, is chief of rheumatology at Cleveland Clinic, one of the most renowned in the country. I do not recall anyone calling it a wonder drug. So I do not think that term has been used that we have heard, so I do not know who does, but none of our witnesses have.

Mr. BENNETT. Dr. Jacob himself, I believe, certainly on "60 Minutes" last night, accepted the fact that yes, in its early days that is the way it was acclaimed. I do not think the scientists have said that in recent years. But the Mexican thing has made it so to the arthritis sufferer, to the public.

Ms. OAKAR. We do not want people to go to Mexico. What does the Arthritis Foundation recommend for its members in the relief of arthritis; anything?

Mr. BENNETT. Oh, yes.

Are you talking about rheumatoid arthritis?

Ms. OAKAR. Let's say rheumatoid arthritis.

Mr. BENNETT. Do you want me to go into the basic plan in brief? It is a combination of medication, rest and exercise. That is a very oversimplified summary of it.

Ms. OAKAR. What medication specifically do you recommend?

Mr. BENNETT. The Arthritis Foundation reflects the recommendations of the experts; we do not make the recommendations ourselves.

Ms. OAKAR. What do the experts that you quote——

Mr. BENNETT. Aspirin is usually the drug of first choice. In those patients who cannot tolerate it in the dosage that is necessary to keep their inflammation under control, or in whom it does not work, then there are other somewhat more complex drugs that are tried in turn.

You are dealing with a disease for which there is not any cure. Therefore, the problem is to try to keep everything under control. There is a certain amount of trial and error because patients vary so much from one patient to the next.

Ms. OAKAR. You are familiar with the fact that new studies have found that aspirin really is counterproductive. Some studies show that it produces an abnormally low ascorbic acid or vitamin C levels. I am a lay person concerning this, but isn't it an essential in collagen formation? At times it seems what we have traditionally recommended for some older Americans is the worst thing they can

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get in some cases. I am just wondering why we are perpetuating this. If there is some question about this, why hasn't the Arthritis Foundation come out and asked about it?

Also, earlier we heard from Dr. Scherbel indicating that it does produce—though he wants the option of using aspirin—it does produce other negative effects, blindness, hearing, et cetera.

Can you tell me a little bit about the Arthritis Foundation because we did not have any kind of preview. How is it funded?

Mr. BENNETT. It is funded almost entirely by public contributions. It is a voluntary health organization, comparable not in size but in operation and function to the American Cancer Society, the Heart Association, and so forth.

Ms. OAKAR. We asked the question of the physicians if they were tied into any special interest groups and I hope you will not be offended if I ask you if you have gotten any contributions from any of the, let's say supporters of aspirin, cortisone, or drug companies.

Mr. BENNETT. From the pharmaceutical houses?

Ms. OAKAR. Yes.

Mr. BENNETT. Yes, the Foundation does get grants periodically. In the area of education, for example, if we propose to carry out a professional program helpful in updating the practicing physician in arthritis, drug firms will support something like that with no more quid pro quo than a credit line that says, "made possible by a grant from X Company."

Ms. OAKAR. You mentioned you do not want to see older people especially ripped off with respect to this drug, and we have heard testimony, and I saw "60 Minutes" myself, that indicated it cost about $4.25. So if it were on the market it would be a lot cheaper than other drugs, wouldn't it?

Mr. BENNETT. Oh, yes.

Ms. OAKAR. How would they get ripped off financially by taking this drug?

Mr. BENNETT. In the Mexican connection——

Ms. OAKAR. I am really talking about getting treated here with the drug.

Mr. BENNETT. I doubt that there is a "ripoff" situation there, unless a patient is taking it because it has been promoted to him in some way that makes medical claims for it that have not been verified, for which there is not evidence.

DMSO is not a quackery drug in this country. I say it is a quackery drug the way it is promoted by Mexico. It is still a remedy which is going through its trials.

Ms. OAKAR. You are pretty locked in with the findings of FDA; I mean the credibility of the other doctors that we have heard from are not weighing as heavily, I take it, as some of the studies.

Mr. BENNETT. Yes. The Arthritis Foundation does not consider it its function to tangle with the FDA.

Ms. OAKAR. Why not, if they are wrong?

Mr. BENNETT. Well, I do not think we have the mechanism to determine whether they are wrong. If somebody else does, and the FDA is accused and found guilty and proved wrong, then that might conceivably call for a different point of view on the part of the Foundation.

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Ms. OAKAR. Well, look, you are in the business of giving advice. You are a foundation and have specific dealings with one really problematic disease in this country—it affects people from the cradle to the dawn of life—arthritis.

Do you investigate things initially or on your own or do you pretty much go by what the FDA does?

Mr. BENNETT. Are you talking about legitimate remedies?

We get involved in trying to help investigate unproven remedies, things associated with some kind of questionable claims. Many such problems are not necessarily outright quackery but quasi-quackery, or sometimes simply a legitimate remedy that has had premature publicity, or anything that makes that hardcore desperate arthritis public clamor for it when they cannot get it.

We seek to find out what the facts are and pass on the word. That message is often something like this: "The remedy may prove effective 5 years from now, you cannot get it now, we are sorry you have to wait".

Ms. OAKAR. Have you done an independent study as a foundation of this particular drug, DMSO?

Mr. BENNETT. No. Our research funding mechanisms are not set up to provide direct project support. However, I do not question that the Arthritis Foundation would offer all kinds of help in ways other than funding to try to get appropriate testing carried out.

Ms. OAKAR. You are pretty much predisposed against this drug, are you not?

Mr. BENNETT. No. I am disposed toward truth and predisposed against—well, the agitation that has gone on over this for so long. I do not think that helps us arrive at the point that everybody wants to arrive at.

Ms. OAKAR. That is what we are interested in, as expeditiously as possible getting on with the truth.

Mr. BENNETT. Precisely.

Ms. OAKAR. Thank you very much.

The CHAIRMAN. Thank you.

Mr. Bennett, just one more question.

I assume that because of your deep dedication to helping the people who have arthritis through your foundation that if a new application should be presented to the Food and Drug Administration and the evidence should show that the application is supported as the law requires for approval, and the Food and Drug Administration should, upon that record, approve it and find it desirable in the treatment of arthritis, you would welcome that information, I guess?

Mr. BENNETT. Indeed we would, and we would be among the first to try to pass the word about it.

The CHAIRMAN. Very good.

Well, thank you very much, Mr. Bennett. We appreciate your being here. Just wait a little bit if you will. Our next and last witness is Dr. John Baum, Director of Arthritis and Clinical Immunology at the Monroe Hospital, Rochester, N.Y.

Dr. Baum, we are delighted to have you here. Thank you, as we did Mr. Bennett, for waiting until the end of the day on account of our long calendar here today and number of interruptions. We are

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glad to have you. Will you please make whatever statement you wish to make? It will be admitted in the record in full.

STATEMENT OF DR. JOHN BAUM, DIRECTOR OF ARTHRITIS AND CLINICAL IMMUNOLOGY, MONROE HOSPITAL, ROCHESTER, N.Y.

Dr. BAUM. I would like to point out that I was a member of the National Research Council National Academy of Science Committee that was formed to study DMSO.

I might correct a slight misstatement that was made by Dr. Jacob. I myself, and many of the other members—in fact, I selected the subcommittee members—of the subcommittee used DMSO on patients, as I did myself.

I notice I left out scleroderma, because I also treated a patient with that. So I and the other members of at least my Subcommittee on Connective Tissue Diseases, including Arthritis, had used DMSO. I think it is an interesting drug.

The statement that was read by Dr. Crout was the one that I wrote as the member of the committee responsible for its use in rheumatologic diseases. I made some statements in 1975 which I have had no reason to change in the past 5 years, because as far as I have been able to see from following the literature, I have not seen anything that would make me change my mind.

For example, I do not believe that this drug has been proven to be an anti-inflammatory drug in humans. I do believe as you read out from my statement that it is an analgesic.

As Dr. Reedy did, I have used it on others—as well on myself—for an acute inflammatory injury. But that was for pain—I mean an acute injury. I have seen nothing yet which has convinced me that it does have an effect on inflammation. The best study of this type was done by the Japanese Rheumatism Association. They studied over 200 patients with rheumatoid arthritis which is an inflammatory type of arthritis.

They did find an influence on pain. There was a decrease in pain reported by the patients. But by measurement of the joints there did not seem to be any marked decrease in the size of the joint. If the drug had been anti-inflammatory you would have expected to see some decrease in size of the joint. We find this, for example, when we use anti-inflammatory drugs. Osteoarthritis is interesting because this is a disease where pain sometimes is the greatest problem. Yet there has not been a good study on the use of this drug for the relief of pain in patients with osteoarthritis. I find this to be a definite lack.

The problem with scleroderma, this has gone on for a number of years. I really think Dr. Scherbel and the FDA should get together and look at all of his patients.

In 1965 Dr. Scherbel had already treated 44 patients with scleroderma. He probably has treated—with DMSO—more patients with scleroderma than anybody in the world. So I think a review of all the patients that he has treated might be in order. I have never seen a publication by him in which he put all the cases he has treated together. I think that would be worthwhile.

There are other life-threatening diseases that we deal with in which this drug has not been used, and I think justly so. For

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polymyositis, which can be a devastating disease involving the muscles, you have to use, really immediately, large doses of corticosteroids. I do not know of anything else right now I would take a chance on using. The main point that I brought up, which is in the statement I have submitted, is that I think it might have, as I mentioned before, a role in acute injuries, where its analgesic effects can be more readily used.

I think really what I am expressing again is very much the statement that was made from that Ad Hoc Committee. We looked very hard at over 1,000 references and could not find proof of the efficacy of this drug.

Now, I am a member of a group for U.S.-U.S.S.R. studies in rheumatology. I have made trips there and been at the Rheumatism Research Institute in Moscow, which is their chief research institute, as well as the one in Vilnius. And frankly, although they have it in their formulary but going through the wards and seeing the patients; I had never seen DMSO used by the Russians.

I have visited and lectured at many major universities in Japan. Again, I investigated the wards to see the patients and it is not used widely there. I do not know why, because the drug is available for use in those countries but yet the rheumatologists there do not seem to use it.

I think that is all I have to say at this point. It is getting late.

[See app. 10, p. 137, letter from Dr. Baum.]

PREPARED STATEMENT BY JOHN BAUM, M.D.

My knowledge of this drug is from my work as a member of the National Research Council—National Academy of Science Committee that studied DMSO. I worked on this panel from 1972 to 1974. As a member of this council I reviewed hundreds of physician's statements on the use of this drug and in addition reviewed with the panel over 1000 publications on its use. I have also had personal experience using this drug in the treatment of osteoarthritis, bursitis and acute soft tissue injuries.

Dimethyl sulfoxide (DMSO) is an interesting drug, which has still to find its proper place in the medical armamentarium. Although there are over 1,000 references in the world literature to the various facets of this drug's pharmacology, structure, and use, it is difficult for us to pluck out of this morass a well-defined picture of how it can be used.

There are some glimmerings in the field of rheumatological disease. This material can probably be utilized as a definitely helpful adjunct therapy in some areas of the field.

At the present time there is no clear-cut evidence that DMSO has any effect on any of the basic disease processes of the connective tissue diseases. The possible role of DMSO in a few fields will be discussed.

Only a limited number of studies have been performed in which DMSO has been used as a form of therapy for osteoarthritis. In this condition, in which pain is a prominent feature and analgesics are required, DMSO might play a role because of its local analgesic properties.

It may also be useful in the treatment of rheumatoid arthritis. Though no good studies have been made to prove this, the idea is based on a study performed by a group of Japanese rheumatologists who used DMSO in the treatment of patients with rheumatoid arthritis. Although their methods present problems, in general this was well done; the major effect of DMSO appeared to be relief of pain, with no apparent effect on the inflammatory processes. Treatment of rheumatoid arthritis requires drugs that are both analgesic and anti-inflammatory. (Parenthetically, in osteoarthritis, where there is little or no inflammation, the analgesic properties of DMSO would probably play a greater role.) We do have pure systemic analgesic drugs such as codeine and acetaminophen, but occasionally these all produce side effects that necessitate their abandonment in therapy.

One of the most controversial subjects in discussion of the use of DMSO is the treatment of scleroderma. On the basis of what has been published in the world literature, it is hard to come to a firm conclusion on the role of DMSO in this

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disease. Some authors have claimed that it softens the skin. Other studies by equally reputable authors have not found this to be true to any marked or beneficial degree. Some have reported that peripheral skin ulcers were healed, while others have found that new ulcers appeared even while patients were being treated with DMSO. Most investigators who have used this drug in the treatment of scleroderma appear to agree that it has little or no effect on the progression of the systemic disease.

There has been limited use of DMSO in the treatment of polymyositis and polyarteitis nodosa. These diseases, however, are life-threatening, and are so definitely inflammatory in nature that it would be unwise not to treat them vigorously with anti-inflammatory drugs. I doubt that DMSO would play much of a role in these conditions.

It might be of some use as an analgesic agent in ankylosing spondylitis.

In acute traumatic injuries, sprains, and other such conditions in which early analgesic therapy is required, I think that DMSO would have an important role in therapy, because of the rapidity of its action and the simplicity of its application.

The CHAIRMAN. You are aware of the fact that you indicated in your statement that DMSO does seem to have efficacy in the restraint of pain?

Dr. BAUM. Yes. I think DMSO is an analgesic agent.

The CHAIRMAN. And also "in acute traumatic injuries, sprains, other such conditions in which early analgesic therapy is required," you think that DMSO would have an important role in therapy "because of the rapidity of its action and the simplicity of its application?"

Dr. BAUM. Yes. When I say a role in therapy, I mean I would not use it by itself. I would use it for its analgesic effect. But I also would be careful, if it were an ankle, I would pack that ankle in ice, a good early form of standard therapy. I think several forms of therapy might be necessary and that would be one of them.

The CHAIRMAN. The area of pain and therapy, are those the only two areas in which to your present knowledge DMSO has been helpful?

Dr. BAUM. From the literature that we reviewed and from my own experience, yes.

The CHAIRMAN. You said in the case of arthritis, you noticed that it reduced pain but you took measurements of the joints and did not find any reduction of the inflammation?

Dr. BAUM. This was a study done by the Japanese Rheumatism Association. It was the largest study of its type and I thought a particularly well-done study. It had some deficiencies but in general it was good. They definitely found decrease in pain in the knees, when they applied DMSO, but they measured and did not find any decrease in the size of the joint.

The CHAIRMAN. By the way, did you ever use or know of anyone else using DMSO with respect to shingles?

Dr. BAUM. This was reviewed in the report. I was not responsible for that part of it. I do not really know too much about its efficacy in shingles. I think that was controversial too. Some people said it worked and some said it did not.

The CHAIRMAN. Well, if it would restrain pain in shingles, that would be quite a relief.

Dr. BAUM. I would think so, yes, I would agree with you.

The CHAIRMAN. I remember hearing my mother's doctor, when my mother had a severe case of shingles, that a nerve around the body is inflamed, the doctor made the statement to me and to her

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that the two most painful things he knew were childbirth and shingles.

My brother right now has shingles. Anything that would relieve the pain would be quite welcome to him.

Dr. BAUM. I certainly agree with you.

The CHAIRMAN. One other thing.

Are there other drugs now being used with respect to arthritis, effective in doing anything other than reducing pain? Aspirin?

Dr. BAUM. Yes. Aspirin is an anti-inflammatory agent, as Dr. Scherbel pointed out, a drug known for hundreds of years. Studies have been done of hundreds of patients comparing them—patients who got no aspirin in the form of placebo, versus aspirin, there was an improvement, a diminution in the size of the joint, and some measures of inflammation in the body were reduced when given aspirin. But all analgesic nonsteroidal inflammatory drugs are also effective in that way.

The drugs not effective in reducing inflammation are drugs like Darvon and Tylenol. These are analgesic drugs but are not anti-inflammatory. For the treatment of rheumatoid arthritis, because it is an inflammatory disease, you must give an anti-inflammatory agent as well as an analgesic agent.

The CHAIRMAN. You agree with what was said by one of the other witnesses, that Dr. Scherbel has done creditable work?

Dr. BAUM. Oh, yes.

The CHAIRMAN. The results of his work would be relevant evidence in your opinion to be considered by the Food and Drug Administration?

Dr. BAUM. Certainly if I were to evaluate anybody's evidence, I would evaluate Dr. Scherbel's first, because of the vast experience he has had with the drug. He would be the first one I would go to to evaluate what he has found with this drug.

The CHAIRMAN. But material of that sort was not included in the previous applications which were denied?

Dr. BAUM. I do not know. I do not know about what goes into the FDA, I am not a member of any of their committees, so I do not know what was submitted to the FDA. But I do know that he has worked on this drug, as I say, and this disease for more years than anybody else.

The CHAIRMAN. If after a fuller study of this substance—do you call it properly a drug or just a substance?

Dr. BAUM. Well, I suppose anything that you give to a patient to affect a change in a disease I would call a drug, and if so, by that definition I would call it a drug.

The CHAIRMAN. If further study of this drug should be made and controlled studies could be carefully prepared and presented to the Food and Drug Administration, such as to justify and to bring about a favorable action of that product upon the application so that that drug might become available for general use, I guess you would welcome it, too.

Dr. BAUM. Oh, I certainly would. I treat patients with scleroderma. Dr. Scherbel is right, that is the worst disease I have to treat. I have nothing—well, there is one drug we are trying but there is really very little I have to offer these patients.

The CHAIRMAN. Thank you very much, Dr. Baum.

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It may be that Ms. Oakar would have a question.

Ms. OAKAR. Just very briefly.

Doctor, thank you for again your patience in staying so long with our committee. Doctor, you were a member of this advisory committee?

Dr. BAUM. The ad hoc committee.

Ms. OAKAR. What was the function of that? I am a little confused, all these different committees?

Dr. BAUM. This was the ad hoc committee on dimethyl sulfoxide, which was supported by a contract of the Food and Drug Administration with the National Academy of Science National Research Council. I was asked to join this by the National Academy of Science. We were asked to evaluate dimethyl sulfoxide as a therapeutic agent.

We had available to us all of the records of all patients who had been treated with dimethyl sulfoxide up to that point, which was 1972, with more arriving all the time. The records filled a room at the National Academy of Science. Those records were reviewed and summaries made and, in addition, I occasionally went into the room and would at random open a box and take out a group of records to go through.

Dr. Scherbel pointed out, and it was true, that as you went through those records the evidence from those records was, unfortunately, very incomplete. The sheet would say, "Diagnosis, arthritis; treatment, DMSO; improved." Unfortunately, a majority of the records were of that order. There really was not enough basis——

Ms. OAKAR. Very simplistic it sounds like.

Dr. BAUM. Yes; many of them were. Not every record was like that. Some of them were beautifully done by people who know how to do drug studies and they did careful evaluations. So many of the records, however, were incomplete that we could not really use them to make an evaluation.

So then we turned to the world's literature; we were helped by Dr. Jacob, who had probably most of the references. We evaluated something like 1,200 references in every language, that was translated for us. So we were able to review them.

I personally reviewed all of the references that were in my area. I cannot tell you how many hundreds there were.

Ms. OAKAR. You have not really been on the committee since 1972 for the FDA, is that right?

Dr. BAUM. No. I think the committee ran through 1974.

Ms. OAKAR. You have not been on it since then?

Dr. BAUM. No.

Ms. OAKAR. Doctor, before you became a member of this ad hoc group, you did do research with respect to DMSO?

Dr. BAUM. I used it. I did not do it with a formal protocol saying I would treat so many patients with this. If a patient came in, I knew about Dr. Scherbel's work so I used it on patients with scleroderma.

Ms. OAKAR. What were the results?

Dr. BAUM. They were inconclusive to me. We treated one girl for about 6 months who had bad scleroderma. She had some resolution over her feet, which was unfortunate because before then she had had scleroderma of her whole leg. After that happened, the fluid

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collected and the skin would break open and fluid came out. I do not know whether the DMSO was responsible for that half improvement.

I used it in some patients with rheumatoid arthritis. It relieved the pain. I tried it in some patients with osteoarthritis. Some of them had pain relief. The pain relief was too short for them to want to keep applying it steadily.

Ms. OAKAR. You do not feel the fact that you were using it prior to being on this ad hoc committee prejudiced you in any way?

Dr. BAUM. No, because I was still using it when I was asked to join the committee.

Ms. OAKAR. Do you think it would be helpful to have doctors who have used it be on a committee that would contribute——

Dr. BAUM. No. I think I agree with Dr. Crout there, that a committee must be objective as far as possible. To be objective, you take the evidence that is presented and whether I have used the drug or not I still have to evaluate the evidence that is presented to me. So I think that the people who would be asked to do it probably would have an open mind, looking at the evidence. There are too many of them. If one person was prejudiced the others could very easily call him down and say "You can't say that because look at the evidence here." So I think with enough people looking at the evidence——

Ms. OAKAR. You have used it, you found it relieved pain and after you studied all this, you came to the same conclusion, right?

Dr. BAUM. Yes.

Ms. OAKAR. Dr. Scherbel has used it, he thinks it is effective, and comes to the same conclusion. I respect your conclusions, they are impeccable obviously.

You mentioned as to arthritis, one of the biggest problems is the pain. Doesn't that in and of itself legitimize the fact that this should be put on the market if it does not cause adverse effects, just the fact that it relieves pain for some people.

Dr. BAUM. Well, I would like to see a good study done on the most common cause of pain and the most common cause of pain in the form of arthritis in the elderly, because I work in a chronic disease hospital and I deal with elderly patients. Osteoarthritis is a disease more of pain than anything else. There is probably some degree of inflammation but I think it is a minimal amount.

I would like to get something that helps these people. They are unhappy, this is an unfortunate thing. I load them up with these analgesic anti-inflammatory drugs and they can get side effects as Dr. Scherbel referred to. The side effects he talked about with aspirin you can get around by giving enteric-coated aspirin, once it gets into the intestine it gets dissolved and you do not get the inflammation in the stomach. The study he quoted made that statement that the coated aspirin did well, but still you do get side effects. It is a tradeoff.

If I use DMSO—one of the groups that tried it said they got a lot of headache and sedation. Well, that might be a tradeoff. My patients might object to that, because some of the drugs I use give them headaches.

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I would like to see such a study, because if there is anything that would help with a disease I cannot cure, I can only treat, I would welcome that.

Ms. OAKAR. If we get an effective variety of painkillers would this not be a financial problem for some individuals who are rheumatologists? Would it not strike a blow to the profession, if you had a substance that was so cheap and that people could apply themselves?

Dr. BAUM. Well, aspirin is still a good cheap drug.

Ms. OAKAR. Not for senior citizens who live on $200 a month. They might have to take four a day.

Dr. BAUM. I do not know, it would depend on how much DMSO would cost once it got on the market, how much you would have to apply, and what the final expense would be. I cannot evaluate that compared to aspirin.

You are right, I try to get my patients on the cheapest drugs. I am in academic medicine. My clinic people are people who cannot afford to go to a private doctor. I want to treat them as cheaply as I can and very often I have to use the cheapest drug that I can.

Ms. OAKAR. Thank you.

The CHAIRMAN. One other question.

In your rather extensive use of DMSO, have you had any patient who had serious side effects or reaction to it?

Dr. BAUM. I had one nurse, a blond, as they pointed out earlier that fair-skinned people have problems, who blistered. I think the drug is essentially safe. In our review we only found one patient who died from DMSO. And that is out of thousands who used it. So I think that in general the drug is as safe, if not safer than, a lot of the other drugs we use, yes.

The CHAIRMAN. Thank you.

Well, thank you very much, Dr. Baum and Mr. Bennett, for your kindness in waiting so long and giving us your valuable testimony. We appreciate it.

That concludes our hearing and we thank all of the witnesses and the people who have cooperated with us today. The record will remain open for 30 days for additional comments.

[See appendix 11, p. 139.]

[Whereupon, at 5:30 p.m., the hearing was adjourned.]

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Appendix 1

MEMORANDUM

March 20, 1980

To Members, Select Committee on Aging

From Committee Staff

Re Briefing Paper on DMSO and Arthritis

I. ABOUT ARTHRITIS

WHAT IS ARTHRITIS?

Inflammation of a joint, usually accompanied by pain and frequently changes in the structure of the joint.

ARE THERE DIFFERENT KINDS OF ARTHRITIS?

Yes, there are approximately 100 different ailments under this heading.

WHAT ARE THE MOST WIDESPREAD FORMS OF ARTHRITIS?

- Osteoarthritis -- a degenerative joint disease afflicting approximately 16 million Americans
- Rheumatoid arthritis -- an inflammatory ailment afflicting 6.5 million Americans.

Osteoarthritis and rheumatoid arthritis are the two most prevalent forms. Other prevalent forms include scleroderma (a hardening of the skin), gout, ankylosing spondylitis, bursitis and tendonitis.

HOW MANY AMERICANS SUFFER FROM ARTHRITIS?

32 million, including some 20 million older Americans.

WHAT CAUSES ARTHRITIS?

No one knows. Heredity, infections and injuries are the most common explanations.

IS THERE A CURE?

No, but the disease can be controlled, and its effects minimized, through proper treatment.

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WHAT APPROVED MEDICAL TREATMENT IS AVAILABLE?

- Medication is the first line of defense against arthritis, with aspirin the most frequently prescribed pain-reliever. Other salicylate and anti-inflammatory drugs may be prescribed when aspirin is ineffective or causes obnoxious side effects.
- Physical Therapy, and exercise, helps maintain normal joint movement and strengthen muscles.
- Surgery, in the most extreme and deforming cases, may be used to replace crippled joints.

WHAT OTHER TREATMENT IS AVAILABLE?

With 32 million potential customers, hawkers and medical quacks have promoted everything from mechanical devices and oddball gimmicks to diet and vitamin cures to dangerous steroid drugs, as miracle treatments for arthritis. None, unfortunately, have proven worthy of an arthritis sufferer's money.

WHAT CURES ARE UNDER RESEARCH?

There is a great deal of research underway to isolate the causes of arthritis on several levels. DMSO (dimethyl sulfoxide) has been touted as a panacea for numerous ailments since the early 1960's. To date, the possible effectiveness of DMSO in any long-term treatment of arthritic disease has not been established. The FDA has approved this drug only for interstitial cystitis in humans (a bladder disease), and for veterinary use at present. DMSO is not approved by the FDA as an anti-inflammatory or anti-arthritic drug.

II. ABOUT DMSO

WHAT IS DMSO?

Dimethyl sulfoxide (DMSO) is a refined by-product from the manufacture of paper, whose medicinal possibilities were first brought to attention in America in the early 1960's.

HOW IS DMSO ADMINISTERED?

DMSO can reach the bloodstream within seconds when applied to the skin. It is commonly given in ointments or sometimes by injection.

DOES DMSO HAVE ANY SIDE EFFECTS?

Garlicky breath and some minor skin irritation are the only documented problems.

WHAT CLAIMS ARE MADE ABOUT THE EFFECTIVENESS OF DMSO FOR MEDICAL USE?

DMSO, purportedly, can --

- Eliminate or significantly reduce pain, inflammation and stiffness associated with ailments such as arthritis, scleroderma, spinal

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paralysis, athletic injuries, and burns;

- Act as a carrier of other substances through its absorption qualities through the skin;
- Heighten the effectiveness of other drugs.

ARE THESE CLAIMS CREDIBLE?

A substantial number of private anecdotal reports are found in medical literature and responses to questionnaires sent by this Committee to veterinarians and rheumatologists, supply a good deal of support for use of this drug. The FDA says there have been no double-blind studies, because no placebo has been found with the same noticeable side-effects.

IS DMSO AN FDA-APPROVED DRUG?

The FDA banned DMSO for use and testing on humans in 1965, but approved its use in the treatment of interstitial cystitis in 1978. The FDA claims there are no conclusive findings as to the effectiveness of the drug and points to the temporary injury to the eyes of laboratory rabbits as an indicator of its possible toxicity in humans. DMSO is approved restrictively for veterinary use.

FOR WHAT TREATMENT DO VETERINARIANS USE DMSO?

Curing lameness and injured joints, loosening stiff joints, and enhancing blood circulation.

WHERE IS DMSO APPROVED FOR WIDESPREAD HUMAN USE?

Within the U.S., in Florida and Oregon; in other countries, for varying restricted uses in Mexico, the Soviet Union, West Germany, Austria, Switzerland, Canada, England, Ireland, China, and in several centers in South America.

ARE OBJECTIVE TESTS FOR EFFECTIVENESS NOW UNDERWAY?

The FDA has authorized only a few tests to study the effects on humans, with a few other applications pending approval.

III. COMMITTEE STATISTICS ON DMSO

The Committee sent questionnaires to numerous professional groups inquiring about their experiences with DMSO. Following are preliminary results:

1. AMERICAN VETERINARIANS -- Of 133 returned questionnaires, 70% have used or prescribed DMSO. Of that experienced group of physicians, 95% claimed DMSO effective for animals and 80% furthered their claims for humans. 16% specifically rejected DMSO for human use.

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2. SCHOOLS OF VETERINARY MEDICINE -- The deans of six veterinary schools had similar opinions on the effectiveness of DMSO. Only one denied its effectiveness for animals and humans. However, only two were willing to support its use for humans.

3. AMERICAN RHEUMATOLOGISTS -- Of 169 returned questionnaires, 20% prescribed or used DMSO in their practice. Of those experienced physicians, 40% believe DMSO is effective in arthritis, 50% do not. Similarly, about 40% believe DMSO should be legalized and 50% responded negatively. Most rheumatologists were reluctant to testify. By and large, their most common response was that objective tests should be instituted at once.

4. PROFESSIONAL SPORTS TEAM PHYSICIANS -- The Committee learned of the apparently widespread "bootleg" use of DMSO in professional athletics. Team physicians, however, were reluctant to discuss this with the Committee. Only 20 of the 110 professional sports team physicians have responded to our January questionnaire. Three admitted usage of DMSO, although eight claimed DMSO is effective in reducing pain or inflammation.

5. MEXICAN CLINICS -- The Committee to date has been able to contact only four clinics in Mexico. Three doctors claimed they did not use the drug. Another reported using the drug on himself and his patients for the last nine years and reports no incidents of toxicity.

6. The Committee has not yet received a sufficient number of responses from INTERNATIONAL RHEUMATOLOGY ASSOCIATIONS and FOREIGN MINISTERS OF HEALTH with which to compile statistics.

7. The Committee's questionnaire to PHARMACEUTICAL COMPANIES brought one line responses. Most firms reported they had not tested the drug and were not interested in doing so.

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APPENDIX 2

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U.S. House of Representatives
Select Committee on Aging
Washington, D.C. 20515
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DIRECTOR OF OVERSIGHT
JAMES A. BRENNAN
ASST. TO THE CHAIRMAN

WALTER A. GUNTHARP, PH. D.
MINORITY STAFF DIRECTOR

January 29, 1980

Dear Doctor:

Your assistance in a matter of some concern to the House Select Committee on Aging would be appreciated.

As you know, one of the major health problems in the nation, and particularly for older Americans, is arthritis. Every year millions of dollars are spent on quack remedies and precious little on legitimate research. This misdirection of funds is unfortunate because we may be on the verge of major breakthroughs.

For the last 15 years, a controversy has arisen about the value of dimethyl sulfoxide (DMSO) for treating arthritis in humans. While a number of foreign countries have approved the drug for this and other purposes, the United States' approval of the drug has been more limited. Nationally, the drug may only be used to treat interstitial cystitis in humans and for veterinary purposes. Two States, Florida and Oregon, have enacted laws to legalize this product for broader human use.

While we have learned that there is both widespread and legal use of this drug in veterinary medicine, and a growing use in professional athletics, some critics still decry DMSO as at best, useless, and at worst, dangerous.

May we have the benefit of your experience with DMSO? Would you please take a moment to complete the attached sheet and return it to me at your earliest convenience?

We appreciate your assistance in this matter.

With warm regards, and

Believe me,

Always sincerely,

Claude Pepper

Claude Pepper
Chairman

Enclosure

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SELECT COMMITTEE ON AGING
U.S. HOUSE OF REPRESENTATIVES
CLAUDE PEPPER, CHAIRMAN

QUESTIONNAIRE TO DOCTORS OF VETERINARY MEDICINE

1. Have you ever prescribed or used DMSO in your practice? _____Yes _____No

2. For what types of symptoms, maladies, or illnesses have you prescribed or used the drug (please list)?

_____

_____

_____

3. In your opinion, is the drug effective in reducing inflammation, pain or other arthritic symptoms? _____Yes _____No

4. Studies with animals frequently form a basis for indicating potential effectiveness and safety of a drug in humans. On the basis of your experience, do you have reason to believe or to conclude that DMSO could be safe and effective for humans? _____Yes _____No

5. Comments: _____

_____

_____

_____

_____

6. OPTIONAL IDENTIFICATION:

Name: _____

Address: _____

City: _____ State _____ Zip _____

Telephone Number: (_____) _____

7. Would you be willing to testify before the Select Committee on Aging on these matters? _____Yes _____No

THANK YOU FOR YOUR ASSISTANCE

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Questionnaire to Doctors of Veterinary Medicine

The House Select Committee on Aging conducted a survey regarding the use of DMSO by veterinarians. A random sample of 250 veterinarians was selected from across the nation.

Of the 134 (54 percent) who responded, 94 or 70 percent had used or prescribed DMSO in their practice. Of these, 85 or 90 percent believed it to be effective in reducing inflammation, pain or other arthritic symptoms in animals. Seventy-five, or 80 percent of those who used the drug believed from their experience in animals that DMSO would be safe and effective for humans.

Some of the symptoms for which the veterinarians used DMSO were: tendonitis, lameness, musculo-skeletal disorders, bruises, arthritic joints, acute inflammation and swelling, chronic inflammation in ear canal, edema, sprains, strains, mastitus, laminitus, splints and other leg injuries in horses, cattle and dogs, intravenously for head injuries in dogs, to relieve spinal pressure due to ruptured interverbral discs and as a carrier for other medications.

Following are comments from the doctors of veterinary medicine:

R. C., Wichita Falls, Tex.—"I firmly believe it is efficacious in acute trauma in humans. I have used it on myself one or two times over a 24 hour period when needed over a bruised or traumatized area (over chin bone), etc., I have no experience with long term use of DMSO on myself or anyone else."

L. R., Detroit, Mich.—"Use with care and good judgment. It is absorbed quickly into system and may be objectionable to humans, i.e., taste."

H. B., Augusta, Ga.—"It can cause undesirable reactions under certain conditions. This would require close supervision by physician and is probably the reason it has not been approved for human use. However, this is true of many medications that are in general use by physicians, only on prescription basis."

W. H., Chattanooga, Tenn.—"DMSO may be used as a vehicle via which cortisone, anesthesia or other medications may be introduced without injections."

M. C., Jackson, Tenn.—"In daily use of this drug, we often contact the material ourselves. After 10 years of use, regularly, we show no ill effects, personally. DMSO is no panacea, but should be ok'd for human use."

L. B., Austin, Tex.—"Haven't used it personally. I know of humans with arthritis who have used it with good results. Side effects—garlic breath."

L. D., Topeka, Kans.—"Have always been puzzled at the slowness with which it has hit the human field. Have used it on myself for arthritis of hand and fingers as well as tennis elbow. Only side effect noted was skin tingling when it was applied too viqorously."

J. L., Napa, Calif.—"In my experience (5 years), I have observed no adverse reactions to DMSO, either in the "Medical Grade" or in the Industrial Grade which I dilute with liquid nitrofurazone. I have used it on myself on several occasions. I feel that the drug has shown sufficient effectiveness in both animals and humans to warrant use in persons suffering from such a debilitating condition as arthritis."

W. G., Harrisburg, Pa.—"Because of the messy application and odor, it is usually a third or fourth choice drug in my practice. The reduction in swelling in acute injuries is spectacular, the relief from pain (antra-articular) due to swelling is marked. I have found no appreciable benefit in chronic arthritis."

M. M., Virginia Beach, Va.—"I have found DMSO to be an outstanding anti-inflammatory agent but have not had the opportunity to note any pain killing properties. I also avoid contact with it since it is readily absorbed through the skin and is reputedly cataractogenic to humans."

E. C., Cranston, R. I.—"DMSO has been used for horses and dogs routinely and safely. I have used it for my arthritis with no ill effects or side reactions."

P. G., Pasadena, Tex.—"Stupid that it is not used in humans. I think entrenched interests have headed it off."

J. T., Clarks Summit, Pa.—"I have used this drug for many years—on all classes of animals and on my own body where indicated. I would not hesitate to recommend it for humans but under close medical attention because overdose or misuse can cause sever irritation."

G. W., Salem, Oreg.—"Overall, I think the body of research data available on the effectiveness of DMSO is more than adequate to support its use on human disease."

B. F., Cheyenne, Wyo.—"I feel the drug has tremendous potential and should be released for extensive use."

L. E., Boise, Idaho—"I have used it on myself and members of my family for joint soreness and burns. It has helped on some cases, other times it has not been effective."

J. B., Albuquerque, N. Mex.—"I have used DMSO two or three times on myself when joints were inflamed due to trauma, and it seemed to help."

S. S., Kansas City, Mo.—"I would be concerned with what DMSO was carrying into the blood stream as it penetrates the skin. There is a distinct possibility that

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products such as soaps, perfumes, deodorants, etc. which would normally be restricted to the skin are going to end up in the circulation: become potentially dangerous."

Veterinarian from Salt Lake City, Utah—"There is no question as to its effectiveness. It works. However, it's no panacea. It works as a carrier of anti-inflammatory drugs (i.e. cortisone) through skin, muscle, joints, etc."

Veterinarian from Abescon, N. J.—"Redness of skin can develop when first applied. It's an excellent vehicle to get other anti-inflammatory drugs into a joint without tapping joint cavity and risking infection."

D. D., Kansas City, Mo.—"In treating animals with the product, I have, in fact, spilled it on myself with no harmful after effects. I have also used it on my thumb which was swollen due to bowling. The results were dramatic."

N. A., Virginia Beach, Va.—"Far too many claims have been made regarding the properties of DMSO. According to what I have learned, this chemical should be considered potentially dangerous to man and animals and its use should be very carefully considered and the results closely monitored for possible side effects."

D. L., Redmond, Oreg.—"We have had elderly arthritis people who have obtained DMSO from other sources, plead with us for the drug because of the relief it has given them."

J. K., Minneapolis, Minn.—"We have used DMSO as a vehicle to carry other drugs into the body. . . . I used it on my shoulder which was hit by a car door. It worked well. I do not have any after effects from using it."

C. Z., Ft. Worth, Tex.—"I have seen no reason to believe that selective and judicious use of this drug produces detrimental effects which outweight the benefits from its use."

T. G., Lancaster, Pa.—"Having once spilled the drug on myself, I can say that it gives one an awful taste for about 3 days afterwards. I doubt that any person would desire that experience."

W. W., Thermopolis, Wyo.—"My results have been inconsistent. In the majority of the cases, though, there has been relief following use of the drug. I have used it on myself with some success also. It is not a panacea but I believe it would be of value in some cases."

D. M., Portland, Oreg.—"I believe DMSO is a powerful anti-inflammatory drug on a par with the corticosteroids and butazolidin and without many of the side effects that have plaqued users of the steroids. It reduces time required for wound healing by one-third. When combined with various antiseptics, it carries such agents deeper into contaminated areas for more effective antisepsis. . . . Its use intravenously in shock and concussion (of the brain or spinal cord) is dramatic and lasting. I have used it for long periods on intervertebral disc syndrome, with no ill effect on the lens of the eye. Most of the uses are, however, for short periods in acute, painful, inflammatory conditions."

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APPENDIX 3

U.S. House of Representatives
Select Committee on Aging
Washington, D.C. 20515
TELEPHONE: (202) 225-9375

To Heads of Veterinary Schools:

Your assistance in a matter of importance to the House Select Committee on Aging would be appreciated.

Our Committee is in the process of evaluating the experience which veterinarians have had with dimethyl sulfoxide (DMSO) -- an industrial solvent which is prescriptive in animals and which has been touted as an effective new drug that might reduce inflammation and pain of arthritis in humans.

Will you please answer the following questions and return this questionnaire to me at your earliest convenience to the address below?

---

1. Have you or your staff had any experience with DMSO? ____Yes ____No

2. For what types of symptoms or illnesses have you used the drug? Please specify: _____

_____

_____

3. In your opinion, is the drug effective in reducing inflammation, pain or other symptoms of arthritis? ____Yes ____No

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4. On the basis of your experience with DMSO in animals, do you have reason to believe that DMSO would be safe and effective in humans? ____Yes ____No

5. We would appreciate having any additional comments you would care to make: _____

_____

_____

_____

6. Would you be willing to testify before the House Select Committee on Aging on this issue? ____Yes ____No

We appreciate your help.

With warm regards, and

Believe me,

Always sincerely,

Claude Pepper, Chairman
Select Committee on Aging
3269 House Annex #2
Washington, D.C. 20515

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Questionnaire to Directors of Veterinary Schools

The Select Committee on Aging asked several directors of veterinary schools for their experience with DMSO. All six of the directors who responded had experience with the drug. Three felt it was effective, one felt it was effective sometimes, another said not at all. One of the directors had used the drug only to carry other drugs into the bloodstream.

Two of the directors believed the drug would be safe for use in humans. Three either felt there was not enough data to warrant its approval for human use or felt their experience was too limited to answer the question.

Following are comments from the directors:

Dr. William R. Romane, Professor of Large Animal Medicine at Texas A. & M. University reported that he had experience with DMSO and had used it for inflammatory conditions of joints and muscles. He found the drug effective in reducing inflammation and felt on the basis of his experience with DMSO in animals, the drug would be safe and effective in humans. He added: "I think it is safe to use in animals and have had no bad reactions from its use."

Dr. K. D. Weide, Director of the Veterinary Medicine Research Farm, University of Missouri at Columbia said he has used DMSO for arthritis in small animals, tentonitis in horses and tissue swelling in dogs. He also found it effective for these conditions and felt the drug would be safe and effective in humans. He said: "This is a good product for reduction of localized tissue swelling."

Dr. D. M. Young, Head of the Veterinary Research Laboratory at Montana State University has used DMSO in tissue (cell) preparation, used occasionally for acute, traumatic arthritis in horses and found that "sometimes" DMSO was effective, especially in acute cases. He felt his experience was too limited to judge whether DMSO would be safe in humans.

Dr. K. R. Van Kampen, Head of the Veterinary Science Center at Utah State University has also used the drug, particularly for laminitis (acute) and hematomata in horses. He added: "(I) have only used the drug on a handful of cases—results have always been equivocal as to whether condition resolved on own or was aided by DMSO administration."

Dr. E. Wynn Jones, Vice Dean of the College of Veterinary Medicine, Mississippi State University, has also had experience with DMSO in induced focal granulating, wounds (controlled—double blind study) in equine and felt the drug was effective in reducing inflammation. He reported that his experience was based only on studies in horses and observed no adverse effect but administration was topical only. He added: "I should, however, elaborate that our observatons concerned only efficacy studies in induced equine model. Since no safety and toxicity studies were conducted and since we are unaware of relevance of equine studies to human safety, I am unable to respond to your question concerning potential human hazards."

Dr. Mahlon W. Vorhies, Head of the Animal Disease Research and Diagnostic Laboratory, South Dakota University reported using DMSO in equine lameness, mastitis and respiratory disease but added, "In my experience, DMSO has always been used to carry another drug or medication. I couldn't make a statement about its use alone. . . . My experiences are clinical in nature and would provide no scientific evaluation."

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APPENDIX 4

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MARY ROSE OAKAR, OHIO
ELIZABETH HOLTZMAN, N.Y.
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THOMAS A. LUKEN, OHIO
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S. WILLIAM GREEN, N.Y.
ROBERT (BOB) WHITTAKER, KANS.
NORMAN D. SHUMWAY, CALIF.
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OLYMPIA J. SNOWE, MAINE
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ASST. TO THE CHAIRMAN

WALTER A. GUNTHARP, PH. D.
MINORITY STAFF DIRECTOR

U.S. House of Representatives
Select Committee on Aging
Washington, D.C. 20515

TELEPHONE: (202) 225-9375

January 29, 1980

Dear Doctor:

Your assistance in a matter of some concern to the House Select Committee on Aging would be appreciated.

As you know, one of the major health problems in the nation, and particularly for older Americans, is arthritis. Every year millions of dollars are spent on quack remedies and precious little on legitimate research. This misdirection of funds is unfortunate because we may be on the verge of major breakthroughs.

For the last 15 years, a controversy has arisen about the value of dimethyl sulfoxide (DMSO) for treating arthritis in humans. While a number of foreign countries have approved the drug for this and other purposes, the United States' approval of the drug has been more limited. Nationally, the drug may only be used to treat interstitial cystitis in humans and for veterinary purposes. Two States, Florida and Oregon, have enacted laws to legalize this product for broader human use.

While we have learned that there is both widespread and legal use of this drug in veterinary medicine, and a growing use in professional athletics, some critics still decry DMSO as at best, useless, and at worst, dangerous.

May we have the benefit of your experience with DMSO? Would you please take a moment to complete the attached sheet and return it to me at your earliest convenience?

We appreciate your assistance in this matter.

With warm regards, and

Believe me,

Always sincerely,

Claude Pepper

Claude Pepper
Chairman

Enclosure

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RHEUMATOLOGISTS

SELECT COMMITTEE ON AGING
U.S. HOUSE OF REPRESENTATIVES
CLAUDE PEPPER, CHAIRMAN

QUESTIONNAIRE

1. Have you ever prescribed or used DMSO in your practice? ____Yes ____No

2. For what types of symptoms, maladies or illnesses have you prescribed or used the drug (please list)?

_____

_____

_____

3. In your opinion, is the drug effective in reducing inflammation, pain or other arthritic symptoms? ____Yes ____No

4. In your opinion, should the United States legalize DMSO for the treatment of arthritis and other diseases in humans? ____Yes ____No

5. Comments: _____

_____

_____

_____

_____

6. Optional identification:

Name: _____

Address: _____

City: _____ State _____ Zip _____

Telephone Number: (____) _____

7. Would you be willing to testify before the Select Committee on Aging on these matters? ____Yes ____No

THANK YOU FOR YOUR ASSISTANCE

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Questionnaire to Rheumatologists

The Select Committee on Aging conducted a survey concerning the use of DMSO by rheumatologists. A random sample of 250 was selected from across the nation.

Of the 169 (68 percent) who responded, 33 (20 percent) have used or prescribed DMSO in their practice. Forty-nine percent of them felt the drug was effective in reducing inflammation, pain or other arthritic symptoms. An additional 23 who had not had experience with the drug felt it was effective in reducing inflammation.

Those who have prescribed or used DMSO in their practices reported using it for the following conditions: arthritis (including osteoarthritis, rheumatoid arthritis and degenerative arthritis of the spine), bursitis, scleroderma, tendonitis, fibrositis, gout, sprains, skin ulcers, painful muscles, cervical syndrome and epicondylitis. A majority of the rheumatologists felt more carefully controlled studies were warranted and should be undertaken on the drug before it is legalized. Twelve (36 percent) of the 33 who had experience with the drug felt it should be legalized.

Following are comments from the rheumatologists:

H. S., Bluffton, Ind.—"I believe DMSO should be treated as all potentially dangerous drugs. That is, it should not be released until carefully controlled studies reveal that it is effective and if so, that the potential benefits outweigh the potential risks of its use."

M. S., Portland, Oreg.—"I have no personal knowledge. This 'drug' is used in Oregon for just about everything from skin rashes to sexual dysfunction. Being a relative newcomer, I am unfamiliar with its full history. Its popularity is such, though, that I'm sure half my patients would admit to using it—surreptitiously and illegally. . . . My personal bias is that DMSO is no more than a topically effective local anesthesia. It certainly does not change the natural progression of articular pathology."

G. S., Portland, Oreg.—"I don't use the agent DMSO extensively but it has been a useful agent with temporary benefit without significant toxicity."

E. R., Belleville, Ill.—"As a rheumatologist, I am concerned as are other physicians about the lag time in obtaining approval for promising drugs. I see no reason to single out DMSO from a number of unapproved drugs for specific action."

E. L., Burlington, Vt.—"I have seen only one patient on DMSO; she had severe scleroderma and felt the drug was softening her skin. I did not follow her long enough to fairly appraise any change, but objective improvement was minimal."

R. G., Abington, Pa.—"DMSO may have great potential and should be easily available for even rather low level sophistication clinical trials, but it should not be available for marketing as an arthritis treatment. The placebo effect is tremendous."

S. A., Arcadia, Calif.—"DMSO does seem to be absorbed through the skin and is somewhat effective in the acute reversible and superficial inflammatory processes such as bursitis. I do not believe that the drug is ready for marketing but should certainly be made available on an investigational basis so that more cogent data can be obtained. Our limited use of DMSO on such a basis sanctioned by Ayerst Laboratories in August 1965 was never satisfactorily completed due to the withdrawal of this preparation from the market. Additionally, there seems to be some suggestive data that DMSO might be helpful in the burn victim."

J. L., Cornwallis, Oreg.—"The needed studies for therapeutic efficacy and safety have not yet been done. The government should sponsor these tests. Then if the drug passes it should be legalized—under the same safeguards as any other drug."

W. B., Charleston, S. C.—"It should be made available for general use. It won't take long to find it's place in treatment. It will probably find use only as a liniment—an adjunct to physical therapy."

R. T., New Haven, Ind.—"I would have prescribed it repeatedly for rheumatoid arthritis and scleroderma if the drug had been available. . . . Dr. Arthur Scherbel of the Cleveland Clinic has had more than twenty years experience with this drug. I trust his judgment as one of the most capable rheumatologists in the United States. This drug is extremely valuable and should be available for study and use."

K. H., Kansas City, Mo.—"Because I am a rheumatologist, I have seen patients who have used it for arthritis and were not benefited. I see many, many patients who have tried all kinds of quack remedies. My partner, Dr. J. L., did research on this drug 8 to 10 years ago and concluded that it was ineffective for rheumatic diseases though it is an interesting and unique drug in other respects. Since it was approved for treatment of a bladder condition it has enjoyed renewed enthusiasm as a quack arthritis remedy but it is in the same unproven category as gold bracelets, alfalfa tablets, yucca pills, garlic pills, snake venom, cocaine, bee stings, chelation therapy, polyvalent bacterial vaccines, ad infinitum."

P. S., Portland, Oreg. has used the drug in his practice for osteoarthritis rheumatoid arthritis, scleroderma, nonspecific periarthritides (bursitis and tendonitis),

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sprains, cervical syndrome, carpal tunnel syndrome. He adds: "These prescriptions were given after considering that the order of toxicity of DMSO is very low, these patients were eager to try it, and would have been exploited while attempting to obtain it without my prescriptions. No one involved has been impressed with its effectiveness. . . . No reason to release a drug until there are established indications for it. Whether we have satisfactory mechanisms for establishing indications, controlling, and releasing drugs is another question."

W. B., Denver, Colo.—"Used topically, it gives some relief but does nothing to alter the course of the arthritis. The risk for abuse of the drug is high—I see many people who have been told they are given it by Mexican physicians."

J. L., La Cross, Wis.—"My only experience with DMSO so far, personally, has been one patient who was here with scleroderma that was receiving DMSO from a physician in Oregon. She used it for the skin component of her scleroderma and claimed that it was quite effective. Indeed, her skin did seem pretty good considering the extent of her scleroderma. I have, of course, read about the use of this drug in multiple arthritic disorders. I would very much like to see more people studying this drug and its use liberalized for this reason. . . . If need be, I would like to see the NIH do these studies much like the current laetrile studies. Much has been written about this drug (as with laetrile). Unlike laetrile, however, I think there may be a foundation for its use in some of these diseases. . . ."

R. E., Tacoma, Wash.—"Effectiveness not established, however, some anecdotal experience by other practitioners I respect, and isolated cases in the literature make it worthy of wider use. I have never, ever seen it hurt anyone."

C. A., Cleveland, Ohio has had some experience with DMSO in experimental use at the Cleveland Clinic on patients with scleroderma. He adds: "It may help . . . the thickening of the skin but not affect the internal aspects of any arthritic conditions. The worst problem is that it raises false hopes in all arthritic persons."

S. Z., N. Miami Beach, Fla. has used or prescribed DMSO for arthritis, nonarticular rheumatism, tendonitis and bursitis and felt it was effective in reducing inflammation, pain or other arthritic symptoms. Although he believes it should be legalized in the U.S., he commented: "I am definitely against any legislation for or against the use of medication. The laetrile fiasco was an example of ridiculous lobbying by uninformed politicians."

L. J., Tulsa, Okla.—"DMSO should meet the same standards as any drug. Clearly the FDA has been arrogant, prejudicial and even vindictive with respect to this drug. It is this type of behavior which Congress must control to decrease the drug lag and increase credibility of the new drug review process."

S. M., Billings, Mont.—"A few patients I have seen reported improvement in scleroderma skin involvement. . . . There is no question that careful clinical trial in humans are indicated especially in Raynard's disease or scleroderma with digital ulcers."

V. F., Pensacola, Fla.—"Most individuals requesting DMSO do so from experience in Mexican arthritic clinics. It is highly unlikely that these patients ever receive DMSO and are actually receiving steroids, and other commonly used tranquilizers, anti-inflammatories."

E. H., Hanover, N. H.—"It should be realized that this compound is used a lot in laboratories for its capability of carrying and penetrating into cell membranes. This is the nature of its usefulness in the skin. It can be painted on the skin and in a short period of time, absorption takes place. Used by itself, it produces an erythema and slight irritation of the skin, possibly a counter irritation and it may be helpful in healing skin ulcers. This experience was accumulated by me at the National Institute of Health in 1965–66 before the FDA ban on use of DMSO. In several patients with scleroderma, it seemed to increase local blood flow somewhat, although we never had solid evidence for this. I certainly don't project that it would be useful for arthritis unless a drug was carried into the joint by its topical application. This seems unlikely however."

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APPENDIX 5

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SILVIO O. CONTE, MASS.
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CHARLES H. EDWARDS III
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MINORITY COUNSEL AND
DIRECTOR OF OVERSIGHT
JAMES A. BERNHAM
ASST. TO THE CHAIRMAN
WALTER A. SMITHARP, PH. D.
MINORITY STAFF DIRECTOR

U.S. House of Representatives
Select Committee on Aging
Washington, D.C. 20515

TELEPHONE: (202) 225-3375

February 29, 1980

Dear Doctor:

Your assistance in a matter of some concern to the House Select Committee on Aging would be appreciated.

As you know, one of the major health problems in the nation, and particularly for older Americans is arthritis. Every year millions of dollars are spent on quack remedies and precious little on legitimate research. This misdirection of funds is unfortunate because we may be on the verge of major breakthroughs.

For the last 15 years, a controversy has arisen about the value of dimethyl sulfoxide (DMSO) for treating arthritis in humans. While a number of foreign countries have approved the drug for this and other purposes, the United States' approval of the drug has been more limited. Nationally, the drug may only be used to treat interstitial cystitis in humans and for veterinary purposes. Two States, Florida and Oregon, have enacted laws to legalize this product for broader human use.

While we have learned that there is both widespread and legal use of this drug in veterinary medicine, and a growing use in professional athletics, some critics still decry DMSO as at best, useless, and at worst, dangerous.

May we have the benefit of your experience with DMSO? Would you please take a moment to complete the attached sheet and return it to me at your earliest possible convenience? Note that the questionnaire is sent "blind" -- that is, you need not sign your name unless you wish to do so.

We appreciate your assistance in this matter.

With warm regards, and

Believe me,

Always sincerely,

Claude Pepper

Claude Pepper
Chairman

Enclosure

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SELECT COMMITTEE ON AGING
U.S. HOUSE OF REPRESENTATIVES
CLAUDE PEPPER, CHAIRMAN

QUESTIONNAIRE TO PROFESSIONAL SPORTS TEAM PHYSICIANS

1. Have you ever prescribed, or your team trainer used, DMSO for athletes in your care? ____Yes ____No

2. For what types of symptoms, maladies or illnesses have you prescribed or seen the drug used (please list)?

   _____

   _____

   _____

3. In your opinion, is the drug effective in reducing inflammation, pain or other arthritic symptoms? ____Yes ____No

4. In your opinion, should the United States legalize DMSO for the treatment of arthritis and other diseases in humans? ____Yes ____No

5. Comments: _____

   _____

   _____

   _____

   _____

6. Optional Identification (please print):

   Name: _____

   Address: _____

   City: _____ State: _____ Zip: _____

   Telephone Number: (____)_____

7. Would you be willing to testify before the Select Committee on Aging on these matters? ____Yes ____No

THANK YOU FOR YOUR ASSISTANCE

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Questionnaire to Professional Sports Team Physicians

Team physicians from professional athletic teams were solicited for their experience with DMSO. Of the 39 who responded, only 7 had used the drug for such conditions as inflammation of joints, sprains, swelling, tendonitis, bursitis, muscle bruises and contusions, and gout. An additional five team physicians has seen the drug used for the same conditions. Ten of the 12 physicians who had used or seen the drug used, found DMSO effective in reducing inflammation, pain or other arthritic symptoms. Most physicians who responded to the questionnaire believed further study was warranted and necessary to determine its safety and efficacy before DMSO should be legalized in the U.S. for treatment of arthritis and other diseases in humans.

Following are comments from team physicians:

R. R., Highland Park, Ill.—"I was an early experimenter with DMSO and the only side effect was the distasteful breath."

R. C., Oregon City, Oreg.—"As I indicated in the responses in your enclosed questionnaire, I feel that at least at this point in time, no ill effects have been substantiated, at least with the topical use of DMSO, and I personally find it as effective as most proprietary counter-irritants such as Ben Gay and this type of readily available remedy. My principal concern about the dissemination of DMSO is that if some of the things should happen nationally that are happening locally, I think it would be cause for grave concern. I would like to specifically call your attention to the fact that DMSO is being injected for treatment of a variety of maladies, and I think that this is certainly premature and somewhat adventuresome at this point in time. At any rate, I think that if DMSO is made generally available to the public, it should be done so in a very regulated manner, and at this point in time, limited to topical use only."

D. A., Atlanta, Ga.—"If appropriate studies could be done to see if there is any objective evidence of the efficacy of the drug, then (I) would favor selected use."

E. M., Baltimore, Md.—"Controlled studies by qualified approved investigators have been and are being done. Would suggest you consult these people. FDA should be able to guide you. If Congress doesn't trust or rely on the FDA, they should improve the FDA."

E. V., Philadelphia, Pa.—"There is enough anecdotal information suggesting this is a useful drug that I feel proper scientific studies should be carried out. I would not use a drug until it has been so evaluated."

T. C., Houston, Tex.—"When used judiciously, this can be a very useful and helpful drug for relieving both short and long term joint symptoms and pain."

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APPENDIX 6

SELECT COMMITTEE ON AGING
U.S. HOUSE OF REPRESENTATIVES
CLAUDE PEPPER, CHAIRMAN

QUESTIONNAIRE TO INTERNATIONAL HEALTH OFFICERS

1. Is dimethyl sulfoxide (DMSO) legal for use in humans in your country? ____Yes ____No

2. For what types of symptoms, maladies or illnesses is the drug legal (please list)?

_____

_____

_____

3. In your opinion, is the drug effective in reducing inflammation, pain or other arthritic symptoms? ____Yes ____No

4. In your opinion, should the United States legalize DMSO for the treatment of arthritis and other diseases in humans? ____Yes ____No

5. We would appreciate any comments you may have: _____

_____

_____

_____

_____

6. Identification (please print):

Your name: _____

Title: _____

Address: _____

City: _____ State: _____ Country: _____

THANK YOU FOR YOUR ASSISTANCE

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DER BUNDESMINISTER FÜR JUGEND, FAMILIE UND GESUNDHEIT

Der Bundesminister für Jugend, Familie und Gesundheit
Postfach 20 04 90, 5300 Bonn 2

Select Committee on Aging
U.S. House of Representatives
z.Hd. Herrn Claude Pepper
712 House Annex 1
Washington, D.C. 20515
USA

Ab 17. 05. 1980 neue Ortsnetzkennzahl für Bonn 02 28
Ab 06. 06. 1980 neue Ruf Nr. 369-1

Ihre Zeichen, Ihre Nachricht vom	Mein Zeichen, meine Nachricht vom	☎ (02221) 834 – oder 834-1	Bonn
3. März 1980	355-5190-01	265	22. April 1980

Betr.: Dimethylsulfoxid

Sehr geehrter Herr Pepper,

wunschgemäß sende ich Ihnen beigefügt den ausgefüllten Fragebogen zurück.

Mit freundlichen Grüßen
Im Auftrag

Feiden

Dr. Feiden

1 Anlage

Hauptgebäude
Bonn 2 (Bad Godesberg)
Kennedyallee 105–107

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SELECT COMMITTEE ON AGING
U.S. HOUSE OF REPRESENTATIVES
CLAUDE PEPPER, CHAIRMAN

QUESTIONNAIRE TO INTERNATIONAL HEALTH OFFICERS

1. Is dimethyl sulfoxide (DMSO) legal for use in humans in your country? x Yes
   ___No

2. For what types of symptoms, maladies or illnesses is the drug legal (please list)?

   As additive in combinations for fungal or viral infections of the skin.
   Claimed to serve as adjunct for penetration of active components into
   the skin.

3. In your opinion, is the drug effective in reducing inflammation, pain or other arthritic symptoms? ___Yes x No

4. In your opinion, should the United States legalize DMSO for the treatment of arthritis and other diseases in humans? ___Yes x No

5. We would appreciate any comments you may have: Claims made in the early sixties for anti-inflammatory effects have not been substantiated. Embryotoxicity suspected with repeated administration in rats (R. Kreutz, D. Wendler: Zbl. Pharm. 116: 131-137, 1977; "EmbryotoxizitÄt von Dimethylsulfoxid")

6. Identification (please print):

   Your name: Peter S. Schönhöfer, M.D.

   Title: Professor, Pharmacology

   Address: Federal Health Office, Institute of Drugs

   City: D-1000 Berlin 30 State: Berlin Country: FRG

THANK YOU FOR YOUR ASSISTANCE

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AUSTRALIA

DR. R. G. ROBINSON
43-3028

NORTH SHORE MEDICAL CENTRE
66 PACIFIC HIGHWAY
ST. LEONARDS 2065

April 24, 1980

Mr. Claude Peper,
Chairman,
U.S. House of Representatives
Select Committee on Aging,
Washington D.C. 20515,
UNITED STATES OF AMERICA

Dear Sir:

I am most apologetic over the delay which has occurred in my responding to your letter of February 29, 1980 regarding the use of dimethyl sulfoxide for the treatment of arthritis in humans. This drug was available some fifteen years ago in this country for a short time but has not been used since. I have had a search of the literature and studied the conditions in various departments around the country without being able to obtain any factual information of the value.

I can say as far as I am concerned that for the short period during which I used this drug it was quite extraordinary in its effects on local conditions. The relief of pain and the improvement in the circulation in many conditions of the hands particularly was quite impressive. The use of the drug in local application was not plaqued with any serious side-effects in short term use as I experienced it but I know of the problems of liver, bone marrow and eye damage.

When comparing it with many of the extremely toxic drugs which are now used, I wonder whether the decision to prevent its use in this country was premature. Unfortunately of course it is widely available and its use indiscriminantly could and probably would create all sorts of problems with toxic effects.

I am therefore sorry to say that I cannot give you any important information about DMSO and I apologise for the length of time that it has taken me to obtain negative responses.

Yours sincerely,

Ray Robinson

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The London Hospital Medical College
University of London
BONE and JOINT RESEARCH UNIT **Telephone 01-247 5454**
Arthritis and Rheumatism Council Building **ext.** 420 421
25-29 Ashfield Street, London E1 2AD. 422 423

Mr. Claude Pepper,
Chairman,
Select Committee on Aging,
712, House Annex 1,
Washington, D.C.
20515,
U.S.A.

EGLB/WMM

12th March, 1980.

Dear Mr. Pepper,

In reply to your letter dated February 29th, 1980, dimethyl sulfoxide is by itself not authorised for medical treatment. It is used as a solvent for drugs used in skin disease such as herpes. An individual doctor however, can prescribe it for the purposes of clinical trials, provided he has the permission of his local ethical committee and the Medicine Commission of the NHS (Act 68 and 71).

My own experience is extremely meagre. Some years ago we used it on the skin in systemic sclerosis without much effect. It has been used more widely in Europe. In general it is not used by Rheumatologists in Great Britain.

I have now retired as President of the European League Against Rheumatism, and my successor is Professor Nassonova, in the Institute of Rheumatology, Moscow. She may be able to help.

Yours sincerely,

Eric G. L. Bywaters, CBE., FRCP., FACP.,

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President:
The Lord Porritt, GCMG, GCVO, CBE, FRCP, FRCS
Chairman of the Council:
Robin Leigh-Pemberton, Esq., DL
Chairman Executive Committee:
Dr. Colin G. Barnes, BSc, MB, FRCP
General Secretary:
M. C. G. Andrews, CBE

Faraday House, 8-10 Charing Cross Road,
London, WC2H 0HN Tel: 01-240 0871

THE ARTHRITIS & RHEUMATISM COUNCIL

For Research in Great Britain and the Commonwealth — Formerly Empire Rheumatism Council

Our Ref: MCGA/AKM

17th March, 1980

Claude Pepper, Esq.,
Chairman,
Select Committee on Aging,
712 House Annex #1,
WASHINGTON, D.C. 20515,
U.S.A.

Dear Sir,

In reply to your letter of the 29th February I understand that some consultants in this country are using DMSO for the treatment of arthritis. However, in view of the lack of clinical trials on this substance it is not possible to assess its effectiveness in treatment.

Yours faithfully,

General Secretary

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Canadian Embassy Ambassade du Canada

1746 Massachusetts Ave., N.W.
Washington, D.C. 20036

April 18, 1980

Dear Congressman Pepper,

Earlier this year you sent a letter to the Canadian Minister of Health and Welfare requesting information about the use permitted the drug DMSO (dimethyl sulfoxide) in Canada. I am pleased now to return the completed questionnaire that you had enclosed with your letter.

If you have any further queries or require more extensive information, please do not hesitate to contact me or my office.

Yours sincerely,

Peter M. Towe
Ambassador

The Honourable Claude Pepper
Chairman
Select Committee on Aging
U.S. House of Representatives
300 New Jersey Ave., S.E.
712 House Annex I
Washington, D.C. 20515

Attention: Mr. Charles Edwards
Chief of Staff

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SELECT COMMITTEE ON AGING
U.S. HOUSE OF REPRESENTATIVES
CLAUDE PEPPER, CHAIRMAN

QUESTIONNAIRE TO INTERNATIONAL HEALTH OFFICERS

1. Is dimethyl sulfoxide (DMSO) legal for use in humans in your country? _X_ Yes ___ No

2. For what types of symptoms, maladies or illnesses is the drug legal (please list)?
For emergency drug release purposes only: (a) interatitial cyatitis - 50% solution (b) scleroderma - 70% solution.

3. In your opinion, is the drug effective in reducing inflammation, pain or other arthritic symptoms? ___ Yes _X_ No (No scientific knowledge from clinical trials).

4. In your opinion, should the United States legalize DMSO for the treatment of arthritis and other diseases in humans? ___ Yes _X_ No (Until clinical trials are carried out under an appropriate IND).

5. We would appreciate any comments you may have: It is believed that the animal toxicology reported many years ago is probably irrelevant for humans, however, the drug should not be encouraged for widespread use until a proper evaluation of benefit-to-risk is definitely established In the above-noted diseases, it is felt that the benefits greatly outweigh any risks involved.

6. Identification (please print):

Your name: Dr. Ian W.D. Henderson
Title: Director, Bureau of Drugs, Health Protection Branch
Address: Health and Welfare Canada
Place Vanier, Tower "B", 355 River Road, VANIER, Ontario
City: Ottawa State: Ontario Country: Canada

THANK YOU FOR YOUR ASSISTANCE

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BRITISH EMBASSY
3100 Massachusetts Avenue, N.W.
WASHINGTON, D.C. 20008
Telephone: (202) 462-1340

11 June 1980

Honorable Claude Pepper
2239 Rayburn House Office Building
Washington DC 20515

Dear Senator

--- I am pleased to forward to you a letter from Mr Patrick Jenkin, Secretary of State for Social Services, in reply to your letter of March 3 about the use of dimethyl sulfoxide in the treatment of arthritis.

Yours sincerely

David Thomas

D C Thomas
Counsellor (Internal Affairs)

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DEPARTMENT OF HEALTH & SOCIAL SECURITY
Alexander Fleming House, Elephant & Castle, London SE1 6BY
Telephone 01-407 5522
From the Secretary of State for Social Services

PO(S of S)2710/3

Senator Claude Pepper
Chairman
US House of Representatives
Select Committee on Aging
Washington DC 20515

4 June 1980

Dear Senator,

Thank you for your letter of 3 March about the use of dimethly sulphoxide (DMSO) in the United Kingdom particularly for the treatment of arthritis. I am sorry that my reply has been so long delayed but I have had to make some enquiries.

DMSO is not licensed in the UK for the treatment of arthritis, and indeed the only licenced use of DMSO in this country is as an excipient in the product called Herpid Solution for the treatment of herpes zoster.

However, under Section 13(1) of the Medicines Act, 1968 it is possible for DMSO (or any medicinal product) to be specifically imported on the order of a doctor for administration to an individually named patient. Though my Department is naturally anxious to improve treatment facilities available for patients suffering from arthritis, it is not directly responsible for assessing the merits of different forms of treatment. This is the responsibility of the medical profession who have to be satisfied that a treatment had been clinically proved before using it.

My Department is of course very conscious of the amount of suffering caused to so many people in this country because of rheumatic and arthritic conditions and it may be helpful if I let you know generally what we are doing in this field.

We consider that research into causation and aspects of treatment for arthritis and rheumatism most important. Most government funded research in this field is biomedical and, under arrangements between this Department and the Medical Research Council, is financed by the MRC, who are kept regularly informed of the Department's interests and priorities. Some of the main areas of interest at present are: the causes of arthritis; evaluation of methods of assessment and alternative physical methods of treatment of arthritic and rheumatic conditions; and studies of the balance of care and

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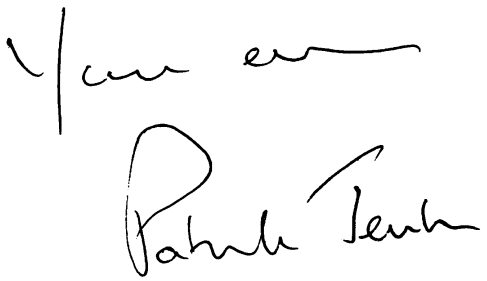
communication between hospital and community services to patients.

Those who wish to undertake research into the causation or treatment of rheumatism and arthritis may apply to the MRC for financial support for projects. An important factor which is at present retarding progress is the comparative lack of interested researchers willing to work on these subjects who possess the necessary scientific skills and expertise. The complexity of modern immunology and biochemistry are such that only the most expert groups can make progress in these very difficult fields of research.

Apart from research into cause and methods of treatment. I should mention the emphasis that has been placed as well on the alleviation of suffering from these painful conditions and helping those crippled by them to live as full lives as possible. In recent years the Department has been devoting special attention to improving rehabilitation services, much of which is concerned with arthritis and rheumatology. By allocating a sum of £1½ million, which was used to make some improvements in accommodation and additions to staff and equipment, the Department has been able to designate 25 demonstration centres in various parts of the country to act as focal points for the development of rehabilitation services, illustrating good practice showing what can be done for the conditions treated at the centres and how services can best be linked with those in the community. Many of the centres specialise in rheumatology and all the remainder do some work in this field. The centres provide courses, demonstrations and sometimes secondments for general practitioners, hospital doctors, nurses, members of the remedial profession, social workers and others interested in rehabilitation. They also carry out research and evaluation of aids and equipment.

Physiotherapists and occupational therapists can do much to help arthritis sufferers to achieve and retain mobility. I am glad to say that the various initiatives we have taken to improve rehabilitation services have resulted in considerable increases over the last two or three years in the numbers of remedial therapists employed in the National Health Service. How far we can keep up this expansion depends of course a good deal on the rate of growth of financial resources that can be made available to the NHS.

I am sorry I cannot send you a more helpful reply with regard to the use of DMSO for treating arthritis but I hope you will appreciate from what I have said that we are fully alive in this country to the needs of arthritis sufferers.



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APPENDIX 7

60 MINUTES

Volume XII, Number 28

as broadcast over the

CBS TELEVISION NETWORK

Sunday, March 23, 1980

7:00 - 8:00 PM, EST

With CBS News Correspondents
Mike Wallace, Morley Safer, Dan Rather and Harry Reasoner

"THE RIDDLE OF DMSO" - Produced by Marion Goldin

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MIKE WALLACE: What is the substance being rubbed on the neck and back of this young woman to deaden the agonizing pain she's suffering after an automobile accident? It's the same substance this quarterback for the Atlanta Falcons uses to override the pain that he says would otherwise keep him from playing football, the same substance that enables this woman, with crippling arthritis, to play the piano again. It's a drug called DMSO. It costs four dollars a quart to manufacture, and you cannot buy it in your drugstore. Tonight, we'll tell you why.

"THE RIDDLE OF DMSO"

MIKE WALLACE: DMSO - 15 years ago news of this potential miracle drug flashed across the medical horizon: dimethyl sulfoxide. It was touted as a pain reliever which would also work miracles on burns, on acne, even on spinal cord injuries; a kind of jack-of-all-trades among drugs. The medical literature was full of stories about it, some of it pro-DMSO, but much of it con, skeptical, even derisive. The Journal of the American Medical Association editorialized against it. And the FDA, the Food and Drug Administration, refused to okay it for general use; said it has never been proved effective. Nonetheless, two states, Oregon and Florida, have legalized it for prescription. And the black market in DMSO has become nationwide. That's how many Americans get it. Meantime, the puzzling story of DMSO continues.

It is largely fueled by the efforts of one man, Dr. Stanley Jacob, an associate professor of surgery at the University of Oregon. For 15 years, this man - some would say this zealot - has been pushing DMSO because he believes so deeply, despite the doubters, in what DMSO can do.

Dr. Jacob, isn't a drug that has so many alleged uses from arthritis to tennis elbow, from burns to spinal cord injuries, from mental retardation to baldness. Isn't a drug like that automatically suspect?

DR. STANLEY JACOB: No question. And I think that that's one of the reasons it's having problems. And if I had it to do all over again, maybe the major mistake that I made, Mike, in the beginning was to tell it the way it was. I think if I would have said it was good for a sprained ankle, but only if the ankle sprain were on the left side, DMSO maybe might be approved today.

WALLACE: Because its use is legal in Oregon, patients make the journey to Dr. Jacob's office there almost as if it were a domestic Lourdes. As we've seen, Dr. Jacob treats some of his patients topically for their bruises, their aches and pains; but some others of his patients, some of the most desperate, are young people left paralyzed from auto and motorcycle accidents. These he gives DMSO intravenously to relieve the pressure on their damaged brains, to reduce the swelling in the brain or spinal cord. And sometimes, apparently, he gets dramatic results.

MRS. WEBER: It took the swelling out of the spine, and they told my husband on the phone that I would— I'd probably be in a chair, paralyzed, for the rest of my life. And so, we're really excited with the results.

WALLACE: Another Oregonian, transplanted to Georgia, swears by DMSO. June Jones is second-string quarterback for the Atlanta Falcons. Time was, he says, he could hardly raise his arm to throw a football. He said he'd be out of the game without DMSO.

JUNE JONES: My problem is in my shoulder, so the simple thing for me to do is I just put this on like this.

WALLACE: Just that much, about an inch worth?

JONES: I put about an inch worth, and I'll rub it-- rub it all around the area. And I'll just leave it sit - sometimes I put on a little bit more than that—

WALLACE: Uh-hmm.

JONES: --and I'll just let it sit like that for, oh, anywhere from twenty minutes to thirty minutes, fifteen to thirty minutes. And—

WALLACE: Boy, it smells, already!

JONES: Yeah, it— in fact, in about, well, maybe in about five minutes, I'll be able to taste it.

WALLACE: That's one small special characteristic of DMSO - it smells like garlic and tastes like oysters.

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But if you took a big whack during a game, let's say, and it was black and blue, you'd rub it on?

JONES: Oh, yeah. I do this more when I— when I play basketball in the off-season. Sometimes you get kneed in a— in a charley horse.

WALLACE: Yeah.

JONES: Boy, I tell you, those things are painful for days.

WALLACE: Right.

JONES: I put it on right after, and I may not have any pain the next day at all.

WALLACE: Jones says several of his teammates use it too, but they wouldn't talk about it in public, because talk of any drug, especially an illegal drug, is verboten in the NFL.

JONES: In our business, availability is the most important thing. In other words, if a guy gets hurt, he's— he could lose his job. So, when someone comes to me and asks for— me for it, I give it to them. And— whether I'm legally okay to do that or not, I really don't care, the repercussions, because I know I'm going to help somebody.

WALLACE: Perhaps more typical of the legions who depend on DMSO are those who suffer chronic pain. Emily Rudich suffered searing, unrelenting pain from arthritis for years, and she could find no relief, she says, until DMSO. She'd no longer be playing the piano without it, she told us.

EMILY RUDICH: I have some very badly gnarled fingers from arthritis, and the DMSO eases the arthritis right away. It's not a miracle drug, doesn't really cure it, but it eases it.

WALLACE: And it does other things for her too.

RUDICH: I had a fever blister on my lip. I used DMSO three times, and the fever blister went away immediately. I've cut myself in the kitchen, and sometimes quite badly, and have used DMSO on it and the cuts begin to heal right away.

WALLACE: How does DMSO work? What does it do inside your body that kills pain and helps healing? Dr. Jacob gave us a capsule understanding.

DR. JACOB: One is that it blocks certain types of nerve conduction. These are the fibers which produce pain. Second, it reduces inflammation or swelling. Third, it actually improves blood supply to an area of injury. Fourth - and this could be the key - in the test tube in certain types of injury, it literally stimulates healing.

WALLACE: But is it safe to use? We put that question to Dr. Richard Crout, head of the Bureau of Drugs of the Food and Drug Administration.

How many people have died from using DMSO? How many that you know have gotten ill from using it?

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DR. RICHARD CROUT: Nobody's died from using DMSO. It— it's— it's a relatively safe drug, as— as drugs go.

WALLACE: Uh-hmm.

DR. CROUT: It— it causes skin rash where it's put on, or at least redness of the skin. It's caused hives in a few people. May cause headache, nausea, in some people who use it. And it rather routinely imparts a garlic odor to the breath. So it's got side effects that are not entirely pleasant, but it's not been a toxic drug.

WALLACE: It's a safe drug, comparatively safe drug, you would say?

DR. CROUT: Com— comparatively, yes.

WALLACE: So, we come back to the controversy that began fifteen years ago. Dr. Crout insists that, despite these anecdotes, neither Dr. Jacob nor any other scientist has ever really proved that DMSO is effective. They've never proved scientifically that it works for anything other than a rare bladder disease called interstitial cystitis.

DR. CROUT: I think people are— are rooting for the drug, in a sense, rooting for the investigators to come through, give us some— give us the right kind of evidence that stands up under scientific scrutiny.

WALLACE: Well—

DR. CROUT: And that's— that's how simple it is with DMSO.

WALLACE: So, I put a sampling of apparently credible scientific evidence before Dr. Crout.

Are you familiar with "Dimethyl Sulfoxide in Muscular Skeletal Disorders" - Journal of American Medical Association?

DR. CROUT: Yes.

WALLACE: "Topical Pharmacology and Toxicology of DMSO" - Journal of Medical Association.

DR. CROUT: Correct. Right. Uh-hmm.

WALLACE: "A Double-Blind Clinical Study" - DMSO - "for Acute Injuries and Inflammations" - Current Therapeutic Research.

DR. CROUT: Yes.

WALLACE: "Treatment of Aerotitis and Aerosinusitis with Topical DMSO". An entire book on the subject of dimethyl sulfoxide by D. Martin and H.G. Hauthal. So it's not as though this is some quack remedy that a few people have used and swear by. There is a considerable body of scientific investigation undertaken—

DR. CROUT: That's right, with some very key holes in that body of evidence.

WALLACE: And that— and those key holes are?

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DR. CROUT: Controlled trials demonstrating that it really works for some of the claims that it's— that it's touted for.

WALLACE: But controlled trials with DMSO are difficult, because that would involve something called "double-blind" tests, where neither patient nor investigator knows who is getting a drug, who is getting a placebo. And that can't be done with DMSO, because the smell of the drug gives it away. What the FDA says is needed is proper testing, and that, for instance, is to treat comparable groups of patients with and without the drug over a long enough time to evaluate its consequences, good or bad. And this, say the doubters in the medical establishment, has just not been done with DMSO.

The National Academy of Sciences, you know, looked over a lot of the work that has been published about DMSO, right?

DR. JACOB: Yes, they did.

WALLACE: And the National Academy of Science's committee said, in effect, that only a few were scientifically sound, that most of the DMSO studies had been inadequately set up and carried out.

DR. JACOB: I don't agree with that conclusion, because I personally have published several dozen articles on DMSO, and I've been associated with two New York Academy of Sciences symposia. There was no one on that committee, Mike, who had actually ever treated a patient with DMSO, to my knowledge—

WALLACE: Uh-hmm.

DR. JACOB: —and I think that that makes a difference.

WALLACE: This young mother, Sandy Sherrick of Riverside, California, suffered severe whiplash and nerve damage in an automobile accident two years ago. When we first met her last November, she was in agony. No pain-killer, no therapy, no doctor, it seemed, could help.

SANDY SHERRICK: Oh, the pain was extremely bad. I was to the point where I cried continuously. I did not cook meals. I did not clean. I barely got myself dressed.

WALLACE: And this went on for how long?

SHERRICK: Months. They finally got to the point where they just told me, "You're going to have to live with it. The weather's going to affect you, and you're just simply going to have to live with it."

WALLACE: Then she heard about DMSO. And as a last resort, Sandy Sherrick - as you can see, still very much in pain - flew to Portland, Oregon, to be treated by Dr. Jacob. We went with her. She received her first dosages intravenously.

DR. JACOB: This will run in about an hour, an hour and half. . .

SHERRICK: I can taste it.

DR. JACOB: You can taste it?

SHERRICK: Yes.

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DR. JACOB: Ready? Don't be too disappointed if, after the first intervenous, you're not significantly improved.

SHERRICK: Okay.

DR. JACOB: Okay? Let's just see what happens.

WALLACE: Twenty-four hours later, there was no real improvement. Besides, she had become nauseous from the treatment.

DR. JACOB: Bend it to one side, and bend it to the other. Now, do you have any more mobility, or about the same mobility?

SHERRICK: I think about the same.

WALLACE: By the third day, she was feeling a little better. You began to see it in her face.

SHERRICK: Well, I didn't have to take any more medicine.

DR. JACOB: How long has it been since you haven't had to take medicine?

SHERRICK: Over two years.

WALLACE: Before she left for home, Dr. Jacob showed her where and how to apply DMSO topically to her neck and back.

DR. JACOB: Now, when you put it on, don't rub it too hard. You just have to apply it to the skin and it goes in. Let it dry over twenty minutes to a half an hour. It won't be totally dry, but anything left you can just wipe off.

WALLACE: That was last November. This is Sandy Sherrick two months later back at her Riverside, California, home.

SHERRICK: Oh, the pain's gone. The pain is totally, completely gone from my neck.

WALLACE: You— you're serious?

SHERRICK: I'm telling the truth, the honest to God truth.

WALLACE: You can do anything? Can you do housework?

SHERRICK: Yes, I can.

WALLACE: Drive a car?

SHERRICK: Yes.

WALLACE: Lift stuff?

SHERRICK: I have not found anything I can't do.

WALLACE: We asked Dr. Jacob to come on down and take another look at you and to talk to you and us together. Okay?

SHERRICK: Okay.

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DR. JACOB: Now, could you bend your head to the left side? Any discomfort?

SHERRICK: None.

DR. JACOB: Okay, now how about to the right side? Any discomfort?

SHERRICK: No.

WALLACE: Sandy, if you had done this three months ago, four months ago, what would have happened?

SHERRICK: I would have been in pain. He wouldn't have been able to touch me.

WALLACE: When a woman has been in pain for two years, and has an injection of, or topical application of, DMSO and suddenly a miracle happens; when a quarterback for the Atlanta Falcons has been using it off and on for years, and says, "I swear by— I'm telling you my arm is better— I throw faster, straighter, better"; when you get testimonial after testimonial, I ask you, what's wrong with those testimonials?

DR. CROUT: Nothing's wrong with them. They may be right. But they don't get the— the— they don't provide the scientific evidence that's necessary for acceptance by scientists.

WALLACE: It's not just the FDA that's skeptical, not just the medical establishment; the drug companies don't have much enthusiasm for DMSO, either. Why? Jacob and others say it's because DMSO is a common chemical solvent that can be manufactured for four dollars a quart, on which no drug company can get an exclusive patent; therefore, there is no big financial return available.

Did an executive of a major drug company really tell you, Dr. Jacob, "I don't care if it" - DMSO - "is the major drug of our century, and we all know it is, it isn't worth it to us"?

DR. JACOB: I was told that if DMSO were approved, it would be competitive, and— and they didn't hold the patents. Yes, I was told that.

WALLACE: And you will not tell us—

DR. JACOB: I— I would not tell you the— the name of the drug company or the individual.

WALLACE: Why?

DR. JACOB: That's the only question I will not— I will not answer. I'll answer any other question.

DR. CROUT: I think it's a fact of life that drug companies are not going to invest in something unless they think there is some financial return.

WALLACE: But we come back to the main reason for the FDA's objection to DMSO - that a story like Sandy Sherrick's doesn't take the place of a scientific test.

SHERRICK: Well, that's fine. I can understand their feeling. But they've got to be able to look at the test results and take me as an individual. I have no reason to say it does work or it doesn't. All I can say is what it's done for me personally. It worked for me.

WALLACE: Two footnotes. DMSO is now available for treatment of assorted ailments in Western Europe, the Soviet Union, Japan and Latin America. And tomorrow morning in Washington, the House Committee on Aging begins an inquiry into why DMSO is not available to all Americans for any appropriate ailment, including plain and simple pain.

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APPENDIX 8

CLEVELAND CLINIC

THE CLINIC CENTER • 9500 EUCLID AVENUE, CLEVELAND, OHIO 44106, U.S.A. • 216/444-2200 • CABLE: CLEVCLINIC CLV.

DEPARTMENT OF RHEUMATIC AND IMMUNOLOGIC DISEASE
J. D. Clough, M.D. A. L. Scherbel, M.D.
R. S. Krakauer, M.D. C. S. White, M.D.
A. H. Mackenzie, M.D. W. S. Wilke, M.D.
R. J. Scheetz, M.D.

March 31, 1980

Congressman Claude Pepper
2239 Rayburn Building
Washington, D.C. 20215

Dear Congressman Pepper:

I enjoyed participating in the DMSO hearings which you held in Washington last week. Furthermore, the manner in which you conducted the hearings was excellent. Many salient points were brought out by you and members of your Committee which emphasized the irregular manner that FDA has been using to withold the use of DMSO for use as a therapeutic agent.

It is apparent to me that FDA is determined to withold this drug from clinical use indefinitely. I feel certain that they will continue to allow clinical investigation, but clinical studies that are submitted will never be satisfactory for FDA to approve clinical use of this drug.

There is now overwhelming evidence that the drug, used as recommended, is clinically effective and without serious toxicity.

I am now contacting patients with scleroderma who have used DMSO in the past and I am asking them to write to you regarding their impression of this drug.

I feel certain that you and your Committee can be most helpful to the medical profession, as well as to the many patients who are in need of this drug if Congress would pass a bill allowing DMSO to be used by prescription for the indications which we discussed.

It was indeed a pleasure for me to meet you in Washington and I want to thank you for taking time from your busy schedule to hold the DMSO hearing.

Sincerely yours,

Arthur L. Scherbel

Arthur L. Scherbel, M.D.

ALS:sm

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APPENDIX 9

1434 Via Loma
Walnut Creek, California 94598
2 April, 1980

Val Hallamendaris
Commission on Aging
House of Representatives, Annex Two
Washington, D. C.

Dear Val:

I am writing to express my feelings regarding my experiences with DMSO. As a former professional athlete, I had the opportunity to use it because of injuries. The first time was on a jammed thumb on my throwing hand. The swelling was so severe I could not bend it. DMSO was applied and, much to my surprise, the swelling started to leave within minutes. Although my skin blistered momentarily, within three days I was throwing the ball hard again and was able to compete successfully the following Sunday afternoon. I feel this would not have been possible without the benefit of this unusual drug.

I have had other injuries in which DMSO was used and the results were very positive. It was applied to my swollen and strained left knee, my lower back, my jammed little finger on my throwing hand, and my tender and inflamed right elbow.

I must point out that we had an excellent team physician, Dr. Graham Rudy. I relied on his medical advice and guidance and feel he was most instrumental in my over-all success in the N.F.L. He did introduce me to DMSO.

I have played with many other players who have used DMSO to great success. The only draw back I have observed would be, as my wife referred to it, "gross body odor." It did not add much to my social life, but I understand that this has been corrected.

I personally feel there is a great need for DMSO, not only for professional and amateur athletes, but for all persons who suffer pain.

Val, our society is blessed to have drugs like DMSO to help us through our misfortunes.

Sincerely,

Daryle Lamonica
Former Quarterback,
Oakland Raiders

DL:sam

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APPENDIX 10

March 27, 1980

Honorable Claude Pepper
Select Committee on Aging
U.S. House of Representatives
Room 712, House Office Bldg Annex 1
300 New Jersey Avenue SE
Washington, D.C. 20515

Dear Congressman Pepper,

I would like to thank you again for the privilege of appearing before the Select Committee on Ageing. It was an interesting experience for me; first because it was the first time I have ever given testimony before such a group but also it was the first time I had ever attended any type of committee meeting in Washington. I was impressed by your handling of the hearing.

I would like to state, because of its importance, my support of the present mechanisms for handling drug applications. People easily refer to the thalidomide experience as a plus for the FDA but then attack the FDA's method of handling new drug application. Many people all too easily forget that the type of decontrol that some of them are asking for was precisely the type of freedom that enabled thalidomide to get on the open market in Germany and Britain. I to have chaffed under the restrictions of the FDA since I have participated in many drug trials. I do feel that some adjustment of the ways in which they work should be done. I personally favor the use of studies done abroad which have been done by reputable workers with good controls. However, studies of this type are admittedly harder to control and evaluate.

I do not believe the FDA committees are biased. They might err in the direction of being too cautious but that seems to be a problem in much of bureaucracy. You rarely get your hand slapped for being too cautious (although the FDA seems to be an exception) but often do if you are too free with information or permission. I have worked in rheumatology since 1952 (starting as a medical student) and I know virtually every leading rheumatologist in this country. I know them to be a group of individuals who maintain

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objectivity because of the chronic nature of the diseases with which they deal. They must be suspicious of unproven remedies, because of the fear of giving false hope to their patients.

I understand Congresswoman Oakar's statements and in frustration I have occasionally felt the same way about the review of a drug upon which I have worked.

Dimethyl sulfoxide (DMSO) appears to remain a special case. I am frustrated by the lack of studies on conditions where I feel this drug can have a beneficial effect; that is, athletic injuries and perhaps osteo-arthritis. I made this statement in 1974 as a member of the Academy of Science ad hoc committee and I repeated it in 1975 at a conference on this drug which was chaired by Dr. Jacob. I made it at your meeting and it looks as though I will be making the same statement for years to come.

I think that Dr. Scherbel, because of his eminence and work over the years, might provide the impetus for the studies that were discussed. In 1965 he had already treated 44 patients with scleroderma. He continued to treat patients until the present time. There is no doubt in my mind as I stated at the hearing, that he has probably treated more patients with scleroderma with DMSO than anybody else. I feel that he should collect all of his data and publish it so that the medical profession and the world in general for that matter, can see the evidence that he has collected over the years for the efficacy of this drug. I am somewhat saddened that he has not chosen to do so. The followup 15 years later of 40 patients who have been treated with DMSO to see what has happened to their disease would be invaluable. I would even propose that the government support the follow-up of these cases to use Dr. Scherbel's data to help establish what he feels and what Dr. Jacob feels is the value of this drug in scleroderma.

I do not believe that this drug cannot be objectively tested. There is no drug in the world which by proper experimental design cannot be tested. Dr. Crout said the FDA was willing to work and aid in the design of such studies and I believe him. Hundreds of different types of studies of different drugs come into the FDA every year and I am sure that they are better acquainted with the design of drug studies than any place else in the world.

I do not believe that this problem will be settled by rhetoric or an attack on the FDA. It can be solved only by proper investigation that will prove to the physicians the efficacy of this drug. If the drug was to be released without proper evidence, I as a physician would be reluctant to use it and I think that most of my colleagues would feel the same way.

Thank you again, not only for your courtesy to me, but for the members of your staff who were most considerate.

Sincerely,

John Baum, M.D.
Professor of Medicine and
Pediatrics and of Preventive,
Family, and Rehabilitation Medicine

JB:mel

copies to: Congresswoman Mary Rose Oakar
J. Richard Crout, M.D.

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APPENDIX 11

TOUTLE, WASH, *March 19, 1980.*

Hon. CLAUDE PEPPER,
Chairman, Select Committee on Aging,
Washington, D.C.

DEAR SIR: I understand that beginning next week, you will be listening to hearings and testimonies on the controverisal drug, Dimethyl Sulfoxide, better known as DMSO.

Please find attached, my own personal testimony and experiences with the drug, its founder and advocate Dr. Stanley Jacob, and the many people whom I have shared them with.

I sincerely hope that you might take the time to read this paper, and that it will in some small way, help you to reach a favorable decision on whether or not to legalize it, subsequently making it available to the tens of thousands of people who will become victims to head or spinal cord injuries within the next year, according to present statistics.

The only other thing that I could wish from you, would be a chance to meet my son Bill, whose own experience inspired me to write this, for I know you would love him immediately, and be as proud of him as I am. But, as I state in the testimony I have given, I know that also, you would become a believer after having seen the miracle provided my son, through the DMSO; and even more directly, the miracle provided by God.

Your time and attention on this matter will be more greatly appreciated than you can ever know.

Very truly yours,

CLARA M. FOX.

DMSO—THE FACTS FROM A MOTHER'S EYES

Almost since time began (or time as we know it), there have been happenings or events that have had no explanations, so therefore, have been put on record as a miracle. According to Webster's Collegiate dictionary, a miracle means: to wonder at; an extraordinary event manifesting a supernatural work of God; an extremely outstanding or unusual event, thing or accomplishment; a divinely natural occurrence that must be learned humanly.

Under this apt definition, I feel that the story and/or events that I am about to put down here today, fit totally and completely in the above mentioned category. To me, they are nothing short of what we might term a "Modern Day Miracle", with all or most honors for them going to God and to Dr. Stanley Jacob, a professor at the University of Oregon Health and Science Center in Portland, Oregon.

On September 15, 1979, our son was in a very devastating accident which left him completely paralyzed. Through a series of moves after the actual accident, he finally ended up at the above mentioned facility in the surgical intensive care unit, where he immediately received medical attention and care from Dr. George Greccos.

Dr. Greccos met us coming into the hospital, showing us Bill's x-rays and explaining everything to us, leaving nothing at all out. He was very forward and direct while he told us of the possibility of our son not making it, but that he had put him on a purely experimental drug known as DMSO, hoping to avoid this happening. He said that most of the reason Bill had even made it that far was due to his excellent physical and mental condition. He did add however, that if Bill did make it, he would undoubtedly be paralyzed for the remainder of his life, from the point of injury in his neck on down. I would like to point out at this time that I later realized that if DMSO is administered within the first hour to even possibly two hours after injury, that that injury can and will be totally reversed, and that our son did not receive it until approximately six to seven hours after his injury. Dr. Greccos then tried to prepare us for our first confrontation with him.

We followed Dr. Greccos into the S.I.C.U., and that first picture will be forever etched into my mind. It really is quite a shock to see anyone, let alone your child, whom just hours before had been a fun loving and vibrant young man, now just lying with his head cleanly shaven and ugly (but necessary) steel tongs drilled into his head to keep it immobilized and at the same time, thin ropes and pulleys with weights attached to stretch the neck at the crucial point, in order for it to come back into place and hopefully heal. He was to remain in traction for the next six and a half weeks. I might also add, that it was at this time that we first smelled the strange odor which we came to know and recognize immediately through the following days and weeks as the one of only two of the unpleasant effects of DMSO.

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Bill remained in intensive care for the next three and a half days, whereupon he was taken to the ninth floor of the same building and put into the room where he was to spend the next six months.

DMSO as you no doubt already know, stands for Dimethyl Sulfoxide, a non-aqueous solvent that will dissolve everything that water will, plus more, was given to him intravenously for a total of ten days. After several days, he began to have distinct feelings in his shoulders and arms, then in his upper chest to just below what they medically refer to as his nipple level. And before he was taken off the drug, he was even beginning to experience feelings and sensations in his bladder and kidneys, asking for his urinal time and again, and in each case, actually urinating in it. Of course you can imagine the excitement that came with each new discovery.

Also during the course of these ten days and some time after, Bill fought off three bouts of pneumonia and a very bad urinary tract infection. But with each new obstacle, the realization of the fact that DMSO had literally saved his life by drawing the fluid and pressure from his spinal cord and head caused by his injury, and then by the added benefit of all the new feelings he was experiencing, his zeal to fight off these so-called enemies and survive was much increased.

Several weeks later, we were informed that Bill had also destroyed or damaged much of the cartelage in his neck and would have to undergo a surgical procedure to remedy this. This surgery was performed approximately five weeks after the medical staff of the hospital had taken him off of the DMSO, and involved implanting two stainless steel surgical rods in the back of his neck, fused together with some bone and muscle taken from his left hip.

He recovered quite nicely from the operation which was very definitely successful, but as the days rolled by, he seemed to slowly deteriorate and he was continually in a state of pain. This kept him from participating in the physical therapy program with the fervor that was necessary for his improvement and eventual release from the hospital. During this time, we kept applying DMSO topically to all the painful areas in his neck, shoulders and arms as well as much of his body we could reach. This seemed to help minimize the pain, while at the same time we began to notice the very smooth and fluid motions that his legs would make. When explaining this to the staff and students, it was simply dismissed as natural leg spasms, that would occur frequently in the future. Then one day, one of his legs made such a motion while Dr. Greccos was in the room talking to him. He came out of Bill's room with a look quite close to awe and wonderment, and flatly stated that now he realized what we were talking about, and instantly agreed that this indeed was not a regular spasm, but something quite different on which to speculate in the coming weeks.

Shortly after the removal of the drug, and the urinary tract infection had finally been put under wraps, the bladder and urinating feelings gradually left, and Bill seemed to slowly go down hill physically. It was only because of the condition he finally reached, that we managed to get the staff physicians to agree to let us bring him home for Thanksgiving, more or less as a last ditch attempt to start him back on the road to recovery, which it did. However, without the aid of the drug, it was extremely difficult and painful, and he was only managing possibly fifteen minutes to a half an hour of therapy a day, before the fatigue and pain would send him back to his bed.

For close to three months after they took Bill off of the DMSO, we fought daily to have the intravenous procedure continued, without much luck. But we finally got our point across shortly after the Christmas holidays, and they did agree with certain stipulations. The first of these were to agree to let them take him across town to Good Samaritan hospital for a series of neurological tests to be run on him. If these tests gave them any type of room for some noticeable improvement to which they could credit to the DMSO, then they would put him back on it twice a week for a given number of weeks. After that, he would be returned to Good Samaritan for another series of the same tests for a reevaluation. If there were no significant changes, then we were to drop it.

From that time on, Bill quickly and steadily improved, to the point to where he could now tolerate maximum occupational and physical therapy for three to five hours per day without any pain; just sheer exhaustion from working himself so hard. He jumped from lifting two and a half pounds of weights on his right arm and wrist, to between fifty to sixty pounds; and from one and a half with his left arm and wrist to between thirty-five and forty. By being able to accomplish this, he has worked back his tri-flex in the right arm, which up to then had been gone; and I might add, a very good bi-flex muscle of which he is extremely proud of, and ready to take on anyone in a good arm wrestling match. And slowly but surely, the left tri-flex is coming around, and we are increasingly confident that before long, he will also have all of that back.

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Bill has improved so quickly and successfully, and has maintained such a fantastic attitude and spirit throughout this whole thing, that needless to say, he has most of the nursing and therapy staff wrapped quite comfortably around his little finger. Several of them banded together about a month and a half ago, and took him out for pizza and beer on a Wednesday evening. They so enjoyed themselves with him, that it became a weekly ritual to get an evening pass and to take him to dinner and possibly a couple of drinks. Each Wednesday thereafter, they tried to see that each time was to a different place, and try to show him some of their surrounding area. And each time, either his special made splint, or a small material device they made up to enable him to slide his spoon or fork into to feed himself, went along with him. If he slipped up a time or two, he didn't become embarrassed and quit; but threw back his head in a fit of laughter which was quickly caught up by everyone else and the fun continued until it was time to return him to his room at the hospital.

Last Thursday, on March the thirteenth, Bill was finally taken back to Good Samaritan hospital to have the earlier tests rerun and reevaulated. The results as we have been told, were nothing short of amazing. Not only everything in the prior tests showed considerable improvement, but to put the icing on the cake, the new tests also showed that he also had nerve sensory motions in his right foot. Now we are even more convinced and confident that things (miraculous things), are happening to and within him.

Our son will be coming home this Saturday, March the 22nd, which just happens to be my birthday, and this time to stay. Whoever thought that this mother would ever recieve such a very special gift of not only her son's life, but his very being. And believe me, I don't think there could possibly be a prouder mother or family than us; for you see, he will be coming home being able to feed himself, brush his own teeth, shave, comb his hair, partially dress himself, and even bath himself. This young man who six months ago was being prepared for the possibility of a lifetime of complete paralyzation. He also can now even operate his manual wheelchair quite aptly by himself, which he was absolutely unable to do, even just a short month ago. I'm sure you will agree with me when I say, that indeed an extraordinary event and accomplishment that has been learned humanly, has occurred here in the form of one Dr. Stanley Jacob and his miracle drug Dimethyl Sulfoxide.

However, my story does not end here. During the time assessed in the above mentioned account of my son, I have been extremely privileged in being a witness and a part to the whole DMSO story. Bill and I and our family have been able to meet and become friends with some of the most wonderful people in the world, who also share part of this privilege with us.

The first of these is a beautiful young woman by the name of Jennifer Weber, (Jenny) to everyone. Jenny was involved in a fateful automobile accident in which the other driver was killed, just three weeks prior to Bill's accident. Through a similar chain of events, she also was brought to the University hospital very near death herself. Due to the accident, she sustained three fractures of her neck, a broken back, and fractures of both legs, plus her internal injuries. Jenny and her family credit God for giving her the chance to be taken to this particular hospital and in turn, being one of the very first humans to be given DMSO intravenously, and credits He and the drug for saving her life. Jenny went home the eighth of December, still in her halo cast and her right leg in a cast. Today, she no longer wears the halo cast, and the leg cast remains only because she had to have surgery to straighten that right leg up. She has graduated from her wheel chair to a walker; from that to crutches, and just as soon as she gets this new cast off, will be walking strictly of her own volition, and is otherwise as good as new.

Then there is little "Boo". Boo's real name is Terrence Dean and he was brought to the hospital the same day as Bill, but earlier. At the time of his admittance, there was little hope of his surviving. However, they put him on intravenous DMSO, which immediately took the fluid and pressure off his brain, enabling surgeons to operate shortly after to get to the crux of the matter. They found that he had a large mass or network of tiny, miniscule veins covering most of the skull cap and rooting it's way under the skull and over the brain. They removed what they could of it the first surgery; followed by it with another with what they thought was the rest of it a week later, only to find out there was yet more. A week after that, Boo went through yet another surgery, which made three of them in three weeks time. With each surgery however, he continued to improve, though his left side still remained paralyzed. He went home several months ago and is now walking and using his left side almost to maximum ability. Judy and Bill Dean do not hesitate for an instant, in letting you know that they believe were it not for God, and for the DMSO administered upon his admission to the hospital, he would not be with them today, doing once again, all the things that other normal little five year old boys do.

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Still another testimony to the wonders of DMSO is the case of Lynn. Lynn was a nineteen year old college coed when she was brought into the surgical intensive care unit just two days after Bill. She had been beaten sadistically with a three inch pipe and raped; with much further damage being done following that foul deed. She also was given intravenous DMSO upon her arrival, even though she was considered all but dead. Lynn remained in a coma for eleven days thereafter, but suddenly began to show definite signs of waking up. The next day, she was brought up to Bill's floor to a room just next door. Day after day she continued to improve, and she too is now home with her parents and has been for several months. She will undoubtedly be forever mentally scarred by her experience, but physically, she shows every sign of being a normal nineteen year old. Marge and George, her parents, and her family give thanks to God every day for DMSO, for they know that without it, she probably would never have found her way back from the living dead.

Now Terry; he was brought in a few weeks after Bill and had broken his back in a fall from a third story window, paralyzing him from the waist down. He also was given DMSO intrevenously upon his admission, and soon after began therapy. They continued to give him the drug a while longer and suddenly one day, Terry's leg and toes began to move. Shortly after that, Terry was released but is continuing physical therapy on an out-patient basis, and though a bit shakey yet, he is learning to walk again. And he knows though, with great conviction, that through the DMSO the day will soon come when he can walk away from there straight and tall, with a smile on his face that will tell it all.

During the last six months, I have spent many hours in Dr. Jacob's clinic with his beautiful and caring staff, watching miracle after miracle happen right in front of my eyes. I have seen people who have been totally paralyzed for twenty years or more being treated and starting to move. The wonder in their eyes is indeed a sight to behold. I have witnessed the awe in the eyes and actions of a young couple whose young child is being treated for Downes Syndrome, and listen with rapt attention as they relate how far that child has come from Death's door to today. I have sent or personally brought people with various illnesses or pains to Dr. Jacob's clinic and seen them smile with utmost satisfaction at having been cured or helped after years of discomfort and pain. And then I have sat back and watch Dr. Jacob absolutely ecstatic after another successful case or treatment. How very proud and happy he is to be able to help this human race of ours.

I have also done a lot of reading and research into the full and real story of this remarkable drug, and I can only summarize with all my hopes and prayers, along with millions of others, that this humble man can see all his work and dreams materialize into that final success of having DMSO returned to the market by the Federal Drug Administration, so that all Americans might have the chance to be helped or saved through all those efforts. I urge everyone connected with this possibility, to please check carefully all the facts, and help to answer these prayers.

CLARA M. FOX,
Mother of William J. Shaal.

LEVITTOWN, N.Y., *March 19, 1980.*

Hon. CLAUDE PEPPER,
Chairman, House Select Committee on Aging,
U.S. House of Representatives, Washington, D.C.

DEAR SIR: I strongly urge that approval be granted of the drug DMSO.

Having had severe pain due to a knee operation, this drug has helped relieve stress and pain. If it has helped me so much, why can't it be available to others who are suffering?

Your effort in getting action and availability will indeed be deeply appreciated by many people.

Yours respectfully,

MARIE CHAMPNEY.

DIX HILLS, N.Y., *March 20, 1980.*

Hon. CLAUDE PEPPER,
Chairman, House Select Committee on Aging,
U.S. House of Representatives, Washington, D.C.

YOUR HONOR: I wish to congratulate you on the congressional hearings on DMSO.

I have been using DMSO for scleroderma for the past five years, during which time it has proven most effective in arresting my condition, giving me greater mobility of the affected areas and most of all relieving pain.

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I urge you to appeal to the Federal Drug Administration for prompt approval so that DMSO will be available to all.

Very truly yours,

JAMES R. VIDAL.

BEAVERCREEK, OREG., *March 25, 1980.*

Hon. CLAUDE PEPPER,
Chairman, House Select Committee on Aging,
U.S. House of Representatives, Washington, D.C.

DEAR SIR: Congratulations on having the hearing held on the drug DMSO. I hope the hearing on DMSO had as much of a positive effect towards its legalization as the drug DMSO has had in healing my pain.

With as much good as the drug has done and no serious side effects, I would think that would be enough "scientific evidence" to allow it to be legalized. I am sure the value of human life and the lessening of pain in people is going to be important enough to the decision-makers that they will put the people first and authorize DMSO for use.

I, myself, have realized almost complete freedom from pain since being injected with DMSO by Dr. Stanley Jacob. My pain was due to scar tissue formed around the sciatic nerve as a result of two lumbar disc surgeries and would drop me by surprise to the ground—thus causing a constant need for pain medication and the use of a cane, for walking. After two (2) shots of DMSO I was able to quit using the cane, and after about six (6) shots of DMSO by Dr. Jacob I was able to stop using the pain medication. I now feel better than I have since before I got hurt, and owe it all to Dr. Jacob and DMSO. My only reactions to DMSO have been the odor, a mild rash when I use it topically, and a constant up-grading of my physical health. Thank you for your time and efforts to help DMSO.

Sincerely,

PATRICK J. POTTER.

AMERICAN PERSONAL PLANNING SERVICE, INC.,
PORTLAND, OREG., *March 25, 1980.*

Hon. CLAUDE PEPPER,
U.S. House of Representatives, Washington, D.C.

DEAR CONGRESSMAN PEPPER: It was with extreme interest many of us noted your recent House Hearing on the Aging pertaining to DMSO. The absolutely baffling aspect to the whole process is why it has taken until now to bring this marvelous drug to the attention of the American people. Those of us who have used DMSO have known for years of its spectacular properties. We can only conclude that the delay has been caused by uncaring, unelected FDA officials who put personal interests above the human suffering of American people.

God bless you, Sir. There is no more important work you could be doing.

Sincerely,

MARSHALL P. SMITH.

TUALATIN, OREG., *March 25, 1980.*

Hon. CLAUDE PEPPER,
Chairman, House Select Committee on Aging,
U.S. House of Representatives, Washington, D.C.

DEAR SIR: After viewing the "60 MINUTES" program on our TV last Sunday evening, March 23rd on which they covered the DMSO situation, I feel compelled to write you about my own experience with DMSO

In 1973 I found it necessary to have back surgery due to a ruptured disc. As a result of this surgery, I spent four months in a hospital bed with the most agonizing pain possible! After months of tests and therapy, and one year after the first surgery, another ruptured disc was discovered and a second surgery was performed, hoping this would reduce the severe pain. Even tho the main sensory nerves were clipped during this second surgery, the terrible pain persisted for another year. I might add at this point that my work that I loved was a flower shop and garden center that my husband and I owned, and to give up this part of my life was so difficult!

At this point in time, and desperately searching for relief from this persistent pain, my doctors decided another operation to remove three lower ribs might give

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me some relief, so for this I was scheduled. At this time in my life, DMSO came into the picture! A dear friend suggested seeing Dr. Stanley Jacob at the medical school before having this third surgery to see what he might suggest, and bless his heart! He said, "cancel the surgery for now, let's see what DMSO might do first. . . . " Which I did! . . . At that time some "volunteers" on the DMSO program were drinking it, if it didn't help by just applying it to the area outwardly. . . . I DRANK SIX TABLESPOONS OF DMSO DAILY FOR TWO MONTHS! I might add at this point that I was doubtful that *anything* could help my pain trauma . . . the first week I did not notice an appreciable difference, but with each day of the second week, my pain lessened. By the time I saw Dr. Jacob at the end of the second week, I could have shouted for joy . . . and from then on, the pain was less and less severe, until by the time the first month passed, I couldn't believe how much better I felt. . . . At that time Dr. Jacob began cutting down the amount of DMSO I was drinking (incidentally, it was the 70% and I took it in V8 Juice each morning . . .). By the end of the second month, he discontinued its use completely, and from that day, I've been able to live a normal life . . . only in pain when I abuse my back by lifting or doing something I know better than to do!

I don't understand the holding back of such a wonder Drug . . . so many of my friends have had similar great results with it, in so many unrelated situations, with no side effects. . . . HOW CAN WE HELP TO GET IT PASSED BY THE FDA AND AVAILABLE ON THE MARKET?

I sing its praises!

Sincerely,

Mrs. LEONA E. WHITNEY.

Tampa, Fla., March 25, 1980.

Hon. CLAUDE PEPPER,
Rayburn House Building,
Washington, D.C.

DEAR CONGRESSMAN PEPPER: I have had considerable clinical experience with DMSO utilized as an external liniment to various painful joints and other areas of the body. In the past, I have treated over two hundred patients with DMSO products made by Syntex Laboratories.

Most of these patients were benefitted. None of the patients experienced any serious injury to their health. One man did break out with a rash and some pus which resembled impetigo, but this cleared promptly when the liniment was stopped.

I would strongly recommend that this drug be made available to the medical profession, at least in liniment form, because of its effectiveness in relieving muscular and joint pains.

Sincerely yours,

ALBERT A. WILSON, M.D., P.A.

JUNE S. JONES Co.,
March 25, 1980.

Hon. CLAUDE PEPPER,
Chairman House Committee on Aging,
U.S. House of Representatives, Washington, D.C.

DEAR CONGRESSMAN PEPPER: Yesterday I saw on the evening news that your committee held hearings on DMSO. I have been interested in DMSO for several years. I have painful arthritis in my left foot for which I have found no relief except DMSO. In fact I'm quite sure I would find it very difficult to walk at all if I wasn't able to use DMSO. Also I know numerous other people just like myself whose only relief is from DMSO. I am fortunate in that Dr. Stanley Jacob treats me with DMSO, otherwise I'd be like millions of others unable to be treated with it.

I urge you and your fellow Congressmen to do everything in your power to force the F.D.A. to approve the topical or 70% solution for Scleroderma. There are literally millions of our citizens who are being denied access to this marvelous substance because of stupid, negligent, malicious or worse conduct within the F.D.A. towards DMSO. Their constant comments that it has not been proven effective are absolute rubbish. I think there has been a conspiracy against DMSO.

Most every country in the Western World has approved its use. Yet here in the U.S. where it's medicinal value was discovered, our people are denied the right to use it.

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Millions of Americans will be forever indebted to you if you can force the F.D.A. to approve DMSO for scleroderma, because pain sufferers of all kinds can get relief.

Sincerely yours,

J. SHELDON JONES, Jr.

SEATTLE, WASH., *March 25, 1980.*

Hon. CLAUDE PEPPER,
Chairman, House Select Committee on Aging,
U.S. House of Representatives, Washington, D.C.

DEAR MR. PEPPER: Having been a follower of the DMSO program and also a participant, may I please urge you and your committee to press for the release of DMSO by the FDA.

Twenty-two years ago, I had my kneecaps removed and have gone through many setbacks causing me to fall repeatedly on some days. After learning of Dr. Stanley Jacob's studies on DMSO, I became a patient at the University of Oregon Medical Center in Portland, Oregon. This has changed my life tremendously on the positive side. Also I have witnessed great improvement in other patients not only in the arthritic field, but in many other areas. It is marvelous to see their expression of pain relief and their hopeful gains in the medical outlook.

Thank you for your attention.

Sincerely,

DORIS JENNINGS.

SEATTLE, WASH., *March 25, 1980.*

Hon. CLAUDE PEPPER,
House Select Committee on Aging,
U.S. House of Representatives, Washington, D.C.

DEAR MR. PEPPER: For the relief of suffering of arthritis and other painful afflictions and many other medical problems, I urge you and your committee to pressure the FDA into releasing DMSO.

I have been in contact with several people of various ages who have been helped enormously after being administered DMSO at the University of Oregon Medical Center under the supervision of Dr. Stanley Jacob.

Thank you for your attention.

Sincerely,

NORMAN R. JENNINGS.

PORTLAND, OREG., *March 25, 1980.*

Hon. CLAUDE PEPPER,
Chairman, House Committee on Aging,
U.S. House of Representatives, Washington, D.C.

DEAR MR. PEPPER: I am one of many Oregonians who has benefited from the use of DMSO. This drug was obtained from a friend, however, I definitely believe DMSO should be made available to all Americans as a prescription drug.

I do not understand why the FDA has been reluctant in its approval for this drug especially after reading the dangers and side affects of drugs that have been approved.

Please, Congressman Pepper, help this cause by the necessary steps to convince the FDA to release DMSO.

Very truly yours,

PETER D. KRESSE.

LAKE GROVE, OREG., *March 25, 1980.*

Hon. CLAUDE PEPPER,
Chairman, House Select Committee on Aging,
U.S. House of Representatives, Washington, D.C.

DEAR CONGRESSMAN PEPPER: I am writing in hopes of helping you to come to the realization that thousands of Americans are suffering and dying needlessly, simply because we cannot have DMSO. I wish so much you could read some of the pathetic letters from elderly people with various kinds of arthritis, of children with bad burns forming ugly scars that prevent them being able to play, from parents of children formerly hopelessly retarded, and I could go on and on.

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I do feel in fairness to you, I should speak for myself first. I was one of the people who was suffering needlessly and spending large sums of money on useless medical treatment when I was introduced to DMSO 16 years ago. I had severe bursitis in my right shoulder, painful arthritis in my right knee from an old injury, and a degenerative left hip joint. Sleep and rest were something I had not known for many weeks when a friend who had been an arthritic invalid, gave me about 2 tablespoons of DMSO. I applied this to my shoulder twice one evening and fell into a 12 hr. restful sleep. I awakened cured! Needless to say, I was most curious about this strange solution that had done what expensive doctors and shots had been unable to do. I was on crutches and had to lift my leg to put it in the direction I wished to go and lift it with each step when I went to the Portland Clinic, a highly reputable medical association in our area. Their head Orthopedist X-Rayed my hip and said he was very sorry, but nothing could be done for me. Other doctors had shown me some prosthesis and indicated I would soon need a hip-replacement. This top specialist pointed out "rotten bone" below the joint and explained that it would be impossible to attach a prosthesis under these circumstances. I asked about DMSO & he was frank to admit he really didn't know, but felt it wouldn't hurt me, and probably wouldn't help either.

Dr. Jacob accepted me as a patient and explained that DMSO would not cure my condition, but would slow the degenerative hip joint, ease the pain, and he felt time was on my side. I applied DMSO topically 4-5 times a day. In less than a week the crutches were gone. I was soon walking in a normal manner, mowing our large grounds and doing household and gardening chores I hadn't been able to do for some time. One year later, I returned to the Portland Clinic for a check-up, as I frankly felt that it was possible the DMSO was covering the pain but the rotting bone was continuing to rot and I'd get away on a vacation and have the bone break. The same doctor examined me and was amazed as he put me through a rigorous test to see how I'd improved. He sent me down for X-Rays, and when I returned, he hung the new ones beside the year-old ones. As he studied & compared, his jaw almost fell onto his chest and he kept shaking his head in disbelief, or as if to clear his vision. Finally, in answer to my question as to where the rotten bone was, he turned and in an awe-struck voice he said, "Mrs. Ludwig, all I can say is, you'd better go on using DMSO:" The rotten bone was completely replaced by healthy bone.

Two weeks after this, I somehow tripped while hurrying down the basement stairs and I "flew" the rest of the way landing full-force on that hip and my right forearm. At my age, weight, and the momentum I had picked up flying thru the air, I should have broken a good hip. No problem at all. My forearms was like a badly crazed mirro—all black & blue & lumps sticking out as if I'd broken it. My husband had hurried to my aid and I asked for the DMSO. I applied it generously to my arm and in less than one hour, it was as normal as ever.

Four years ago a painful neck condition developed. Topical DMSO did not help me nor did Osteopathic treatments. I had hoped Dr. Jacob would inject my neck, but he refused and told me I must drink 1 tsp. twice a day. The Orthopedist had told me I had two collapsed vertabrae in my neck and there was absolutely nothing that could be done to help me. I had even tried therapy, which only worsened the condition. I drank the DMSO as prescribed in juice or soft drink. In less than 24 hrs, my eyes were so good I had to put away reading glasses dating back to Junior High. I had much less pain, and in two weeks, my neck was 100%—&—has remained so!

My brother-in-law had learned he had a so-called incurrable fungi on his hands when he visited a leading dermatologist in Detroit, Mich. He applied DMSO for 4 days and was so amazed at the results that he could hardly believe it. In 10 days he was 100% cured. That was 6 years ago.

My husband was plagued with sinus for over 60 years. Two applications of DMSO cured him of that problem.

I have used it for severe burns and had the pain stopped at once, & somehow, the DMSO prevents the heat of the burn from penetrating further into the body and damaging more tissue. No blisters, scars, or infection.

With inflation hitting many of us so hard, we can't afford costly medications and doctor bills for every little problem that affects us. We need HELP—&—NOW! DMSO could be of major help to so many of us. We also find it exhausting to wait for long periods in doctors offices as well as try to find means of getting there. DMSO used at home would assist us so much.

You and the other members of our Congress, have it within your power to help. We hope and pray that you will do so & NOW. This is an election year, and many of us are going to be watching how our representatives vote on the practical, sensible things that affect us so directly.

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Please use your influence as Chairman of this Committee, to help the many thousands who really need help.

Yours truly,

DOROTHY S. LUDWIG.

TIGARD, OREGON, *March 25, 1980*

DEAR MR. PEPPER: I have been under DMSO use for arthritis for several months and have no more neck or shoulder pain. Also, pain in hands and wrists cut considerably. I consider the FDA withholding of the use of this drug for anyone needing it a terrible injustice.

Please do all you can to help correct this.

Sincerely,

EVELYN FORD.

BOTHELL, WASH., *March 25, 1980.*

DEAR SIR: After recovering from a crushed spinal disk—due to an accident—I was in intense pain 24 hours a day.

While in Canada one weekend, I was given a bottle of DMSO and used it. I painted my entire back and both hips twice with "Miracle 65" (as it was known then) and have had no trouble since. The doctors I went to just gave me prescription drugs to take and I just didn't want to become hooked!

Thanks for wanting to help people.

Sincerely,

ROBERT L. RUSSELL.

BOTHELL, WASH., *March 25, 1980.*

DEAR SIR: I was introduced to DMSO in 1965. I used it on my right leg and foot. I still have my leg. I had it marked for amputation by three specialists in Seattle but I just couldn't go through with it. Then I found out about DMSO, went up to Canada and got it—used it just once. I had had a repaired bone block of the right ankle in 1926 (polio) and it was poorly done. I don't understand why DMSO can't be legal in our country!

Very sincerely,

LAURA J. RANDALL.

MEMPHIS, TENN., *March 25, 1980.*

DEAR COMMITTEE MEMBERS: Fifteen long years ago I happened to be one of the persons allowed to use DMSO. It was wonderful and gave me the first real relief I had from arthritis of the large joints and the spine. We just couldn't understand why it was discontinued! Now we know! Politics as usual! I have suffered and spent money and time needlessly just trying to be comfortable. No one who has not had this terrible disease can conceive of the pain and soreness it causes.

I had really forgotten about this wonderful drug until I saw "60 Minutes". Now I'm writing you, it really worked. I know. They did test it, as I received it at the University of Tennessee under the care of Dr. Glenn Clark in the Rheumatology Department. At the time, we were also used to test other drugs, but nothing worked for me like DMSO.

Gentlemen, let's get behind this drug and get it on the market. We really need it.

Mrs. REVA GAGGIO.

LAKE OSWEGO, OREG., *March 26, 1980.*

Hon. CLAUDE PEPPER,
Chairman, House Select Commmittee on Aging,
U.S. House of Representatives, Washington, D.C.

HONORABLE SIR: Regarding use of D.M.S.O., from my own personal experience it's most wonderful effect is the alleviation of pain. Secondly, with that effect, it appears to me and my husband, that our own bodies have a renewal feeling and that our own defenses naturally made within the body have a better chance to combat the trouble that is ailing us. We need this product.

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My first experience with it was when I was visiting a friend at lunch, and accidentally a newly poured cup of coffee was upset scalding my legs. I blister easily and blisters were already forming when I peeled off my underclothes. My friend happened to have some D.M.S.O. and advised me to let her try spreading it on the burned area. Within seconds the pain began to subside and the redness faded a little. Two more applications at about ten minute intervals, and a flush still showed but the pain was gone. She gave me a little to take home, and I was able to escape all injury from the burn. Since that time we have found that it alleviates pain from arthritis, sprains, etc., and is invaluable. We do trust that it will become available to the elderly especially, to help with problems of aging bodies.

Several times I have read articles in various publications with testimony of other people who have received relief from pain and problems with this D.M.S.O. To my knowledge it usually has no ill effects, and understand that on some people it causes a rash, which is a minor problem, and goes away. Articles in the Oregonian, a Portland publication newspaper, Oct. 11th and Oct. 14th, attest to the ability of D.M.S.O. in reducing pressure on the brain and assisting accident victims to recover, especially who told me she knows the mother of the young man who had the motorcycle accident described in the article, and that his recovery was miraculous. I do pray that you will give great consideration in your deliberations on this matter.

Yours very truly,

MR. JOHN JAEGER.

WENATCHEE, WASH., *March 26, 1980.*

Hon. CLAUDE PEPPER, *Chairman, House Select Committee on Aging, U.S. House of Representatives, Washington, D.C.*

DEAR SIR: I am writing to you because of my interest in the drug DMSO.

I have first hand knowledge of what this drug will do to help with mental retardation.

Our daughter Melody is an eight year old Down's syndrome child. Our first evaluation of Melody, when she was six months old, was that she would be so severely retarded that in all likelihood she would never progress mentally beyond the age of six years.

When Melody was 11 months old we were fortunate enough to learn about Dr. Jacob and his work with DMSO. He placed her on DMSO at that age. At that time, she couldn't stand because her legs were just like a rag dolls, she couldn't roll from her back on to her stomach, and she couldn't see because her eyes couldn't focus.

After seven years of being on DMSO, Melody has progressed from a severely retarded child to one who is only mildly retarded. She was born with an extremely high roof in her mouth, and now it is within the normal range.

Melody runs, jumps rope, turns summersaults, and plays on a trampoline. She is on a second grade level and excels in math. She has an excellent grasp of mathmatical problems. She is a good reader and a good speller.

Also important is the fact that Melody is quite popular with her classmates—very social minded.

Melody has worked her way up from a class for "trainables" to being in a special education class for educable children. She attends Sunday school with normal children and is planning to go to camp this summer. All of this progress is because of DMSO, so I'm sure you realize why I would like to see this drug made available for suffering people. It certainly offers parents like us a lot of hope.

I understand you're quite a fighter, so I hope you'll be impressed enough with this report to use your influence in the matter of making DMSO available.

Thank you so much for taking the time to read my letter.

Sincerely,

Mrs. DALE CLARK.

DAVID K. PRIEBE, D.D.S.,
EYE AND EAR HOSPITAL,
Wenatchee, Wash., July 10, 1979.

DEAR SIR: For the record I'd like to share some observations about Melody Clark's oral development. Melody has been a regular patient under my care since 11 Aug. 1976.

I have been paying particular attention to tooth size, palate development, maxillary and mandibular jaw arch size, tongue size and nature of dorsal tongue mucosa, all of which have altered developmental patterns in Downs Syndrome children.

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It is my clinical impression that this patient seems to be significantly more normal in every aspect of the above compared with other Downs Syndrome children of similar age. Palate development, while high, has lowered considerably during the time she has been with me. Arch development and particularly tongue seem to be becoming within the range of normalcy.

Behaviorly, Melody has demonstrated that she can handle the stress of dental treatment as well as children not having Downs Syndrome.

Very sincerely,

DAVID K. PRIEBE, D.D.S.

DECEMBER 28, 1979.

In reply to Mrs. Dale Clarks request for a resume of Melody Clark's present economic and social performance, I am enclosing the following information and examples in the area of reading, math, language and social adjustment.

PRESENT LEVEL(S) OF PERFORMANCE

Reading

Able to read fluently from story book to teacher and independently complete comprehension questions on take home at the present level in the Distar Reading Program. (Example 1a). An example of her oral reading, verbal comprehension, and reading rate assessed by the Brigance Diagnostic Inventory of Basic Skills is also enclosed. (Example 1b.)

Math

Able to compute two digit, one column addition and subtraction facts, and is able to write and compute two digit one column addition and subtraction facts from dictated story problems at the present level in the Distar Math Program. (Example 2a. and 2b.) An example of her math skills assessed by the Brigance Diagnostic Inventory is also enclosed. (Example 2c.)

Language

Able to make complete sentences. (Example) The first response in a complete sentence was made in November, 1979. When told at recess that all the balls were being used, Melody responded, "Denise will share with me."

Able to respond to personal data. Gives verbally: Full name, age, address, city, state, birthday, phone number, and parents' name. Able to name in order the days of the week and the seasons of the year.

Social adjustment

Melody had no initial adjustment period after being transferred to the E.M.R. class. She was accepted by her peers on her own personal merit. Melody socializes with her peers at recess and in the classroom. She participates in classroom games and shares classroom responsibilities.

Melody is very conscientious in completing her school assignments, and she is proud of her academic accomplishments.

ROSE M. MULLAN,
Teacher, Wenatchee Special Services.

MELODY CLARK CLASSROOM PROGRESS REPORT: JULY 1979

I would like to address five areas of Melody's functional development in the classroom situation for the 1978/79 academic year. These areas are: reading, math, writing (manuscript), speech and language, and social development.

Math

Melody began the year able to count consistently to ten. She could match numbers to manipulative objects or to groups of objects on paper if the amount did not exceed ten.

Melody has followed the Distar Math I (revised) program and has completed it. Using the Distar format she can count to 100 by ones or tens. She has a good command of her math facts and, when in doubt, she spontaneously uses the correct system to obtain the correct answer without paper and pencil. Melody is able to do story problems, reading the three types of problem (addition, subtraction, algebra) and setting up the proper equation to solve it independently.

In the coming academic year Melody will continue with Distar Math II. This program will begin to introduce fractions at lesson 35, and I see no reason why she

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will have any problem with this. For practical purposes she is now functioning at a beginning second grade math level.

Reading

Melody had been reading in the Edmark program prior to the 1978/79 academic year. She was able to "read" at a high first grade level, but had practically no comprehension. In fact, sometimes she would read the passage from right to left.

Since Fall, Melody has made the transition between a one-to-one sight reading program to the Distar Reading II (unrevised) program. The latter is a phonetic approach to reading. Additionally, she was placed in a small group situation. These are radical changes, and she has made a good adjustment.

Melody is currently reading at an early to mid second grade level within the program. She has mastered the phonetic approach and rarely needs to stop to "sound out" a word within a lesson. She always reads from left to right.

In terms of comprehension, she is reaching the point of being able to verbally answer questions relating to the lesson, but this continues to be her weakest area. However, given the scope of change in format and also that we did not begin her at the start of the program, but rather at about lesson 120, she is showing real progress. She is being given early reading comprehension worksheets to help increase her comprehension and logic relating to what is on paper. Hopefully this will bring her comprehension more in line with her reading abilities.

Writing (manuscript)

Melody can group letters into words and generally maintains her letters within the boundary of primary paper. She copies directly from the chalkboard and many sight words she simply reads and then writes on her paper. (As opposed to having to copy letter for letter, she spells.) She always reads her "boardwork" independently prior to copying it. Her legibility needs more work, but it is readable.

At the start of the year, Melody was able to print her first name. At that point, she was given a "dot-to-dot" model for practice and space to copy directly below the model on primary paper.

Speech and language

While she made herself understood at the beginning of the year, she generally used only one or two word phrases. This, combined with poor articulation, especially of the sibilants, resulted in a lot of situations where we had to say, "show me". However, a formal program with our C.D.S. and patterning of appropriate short sentences which we required her to repeat "Say the whole thing," has led to a situation in which Melody habitually uses short complete sentences about half of the time.

In terms of articulation, I have found that if I pattern a word for her, emphasizing sounds she is leaving out, until she repeats it correctly, she has a tendency to retain the correct pronunciation.

Language and articulation are areas which will need continued support services in the future. However, there has been real growth in both areas this year.

Social development

When the year began, Melody played by herself. She would select a puzzle, poppet beads, or other items and generally return to her seat, even when approached by others. When on the playground at recess, there was a tendency to stand near the teacher and watch the others, or to play by herself.

As the year ended, Melody would not only share play items with others, she would initiate group action. She has learned to jump rope if it is a "single person" rope and she wants very much to participate in "group" jumping where two other persons turn the rope. She will join such groups and takes her turn with the others. She also plays tag with the children outdoors and has generally turned into a very social person.

There is no question that Melody has made great strides in every area of academic and social and physical development this year. The progress is quite remarkable. If it were not for some re-grouping of classrooms and teachers, she would be well placed in an E.M.R. program. For the coming year she can continue to be challenged in this program; but a change in status would not be surprising as she continues to mature and develop the self confidence necessary to perform outside of the security of the classroom.

MARION A. KENNEDY.

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SEATTLE, WASH., *March 26, 1980.*

HON. CLAUDE PEPPER,
Chairman, House Select Committee on Aging,
U.S. House of Representatives.

DEAR MR. PEPPER: The news reports on the recent hearing on making DMSO available to physicians in the United States were encouraging. I am grateful that there is some hope of making DMSO treatment accessible to suffering people throughout our country.

For the past two months I have been using DMSO under the direction of Dr. Stanley Jacob and his staff at the University of Oregon Medical School in Portland, Oregon. Relief from arthritic pain is remarkable. If I waxed as enthusiastic as I truly feel it would make DMSO sound like "Snake Oil from the Medicine Show" and that is not my intent. I want to be completely objective and factual.

I am very fortunate to be able to go to Portland for treatment, but my heart goes out to the millions who can't.

Surely our Government can, and will, exert the compassion and power to see that relief is brought to these unfortunate citizens.

Respectfully,

MRS. GRACE A. WYNNS.

PORTLAND, OREG., *March 26, 1980.*

DEAR MR. PEPPER: My husband and I have used DMSO for years, with success—he finds help for his arthritis and I, as a former fry cook, used it on burns. We think it should be available for everyone—everywhere.

Within a half hour of the "60 Minutes" program, our son called from Nevada saying: "Send me some DMSO." We did!

Sincerely,

VERA R. COWMAN.

TOPEKA, KANS., *March 26, 1980.*

DEAR SIR: The program last Sunday on "60 Minutes" about DMSO and arthritis has stimulated me to write you about my personal experience with DMSO. I have been using it, supplied by Dr. Stanley Jacob, for the past six months and find it very beneficial.

I hope you will use your influence to make DMSO available to other arthritis suffers. True, it is not a cure but can bring wonderful relief, and help make one a happy and useful human being. With all good wishes to you, I am.

Gratefully yours,

Rev. GERALD MCCRACKEN GARDNER.

FT. LAUDERDALE, FLA., *March 26, 1980.*

DEAR CONGRESSMAN. I heard the presentation of the above subject on "60 Minutes" on Sunday, March 23. I also read the news item in the Miami Herald of March 26, 1980 reporting that you chaired the House Aging Committee meeting which urged the Food and Drug Administration to allow widespread use of this "controversial ointment."

You may add my name to those who do regard DMSO as a "miracle drug." Some 15 years ago, before it was banned by FDA, a few applications completely relieved me of an agonizing and excruciating bursitis, which has never returned since. I concluded then, as I have felt through all these years, that DMSO is indeed a wonder drug. I am writing to FDA urging the complete removal of any restrictions to its use, and I would be happy to testify as to my personal experience in support of your Committee's action.

Respectfully,

MORRIS M. WEXLER.

LAS VEGAS, NEV., *March 26, 1980.*

Hon. CLAUDE PEPPER: Before "60 Minutes" was shown on TV, I traveled to Dr. Jacob's for DMSO treatment at the University. I can actually swear and take an oath that it relieved all my pains through my legs and has helped me maintain my job. I am a waitress and all my work depends on my feet feeling good. This drug should be available. I can't understand why people have to suffer, when we all can

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live and work a normal life with this drug available. It's not fair for parts of Europe and Greece, etc., to have it only. The average person can't take the time or expense to travel where its legal to get DMSO.

Please help get the FDA to legalize it.

Thank you,

SHIRLEY STOHLEIN.

BEAVERTON, OREG., *March 26, 1980.*

DEAR MR. PEPPER: My mother has been treated with DMSO for arthritis and is so much better and able to get around with less pain. Anything you can do to see that people needing it for any of several medical problems can have it available, would be doing a great and humane service.

KATHLEEN FORD.

DALLAS, TEX., *March 26, 1980.*

DEAR SIR: I have used DMSO with beneficial effects and it's a crying shame that old folks suffering with arthritis are unable to enjoy the relief, obtainable from its use.

Why can't someone do something to overcome this injustice—Bureaucracy is a terrible monster to behold.

Sincerely,

JOE MASSIE.

PORTLAND, OREG., *March 26, 1980.*

DEAR SENATOR: I hope your committee will make DMSO available to the people of the United States. Speaking as one who suffered severe burns which were treated immediately with DMSO, relieving pain and hastening healing to an amazing degree. I believe it is outrageous the large pharmaceuticals have succeeded in keeping it off the market to protect more expensive drugs. Many intelligent, educated people believe payoffs in high places in the FDA have kept this drug off the market in the U.S. even though it is routinely used in other countries with high standards of health care.

Sincerely,

A. LAYMAN HOFFSTETTER.

MILWAUKIE, OREG., *March 26, 1980.*

DEAR SIR: I am extremely interested in the outcome of DMSO use in general medical practice.

It has proven over 20 years of people usage—obtained from veterinarians, etc., to help senility, mental retardation, burns, sprains, arthritis, skin cancer and other problems. Low cost is a major factor for the elderly.

I am an R.N., I used it on eye bruises following plastic surgery on my nose and my surgeon, Dr. Verner Ludgren of Portland will verify with photos. I have used it on burns—immediate disappearance of any sign of burns and it has helped my aging mother function normally.

Please do not neglect whatever help you can give to further the availability of this substance to the elderly and all people. It has been shoved under the table of red tape, etc.etc. for too long.

I thank you!

Sincerely,

DONNA ANDERSON, R.N.

BOZEMAN, MONT. *March 26, 1980.*

DEAR MR. PEPPER: * * * Much of the credit for a pain-free existence is due to having access to DMSO! And, since I understand this matter of DMSO is to come up before your above-mentioned Committee, I want to add my personal testimony to what may be said.

On October 26, 1977, my wife broke her collar bone. The doctors put a "harness" on her and put her arm in a sling. Despite the doctors assertion that the arm had "healed perfectly" she was in continual pain, and where the break had taken place there was a constant "crunch" every time she moved her arm, and anyone could see

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her collar bone "slip out." She could do no lifting, no pulling, and if she moved her arm forward and up, she would almost scream with agony. Our daughter who lives in Portland, Oregon, was visiting one time when this happened and said, "I have something at home that will fix that up."

This was our introduction to DMSO. Just two applications and my wife had no more pain. After six applications, she has never had to use DMSO for that any more. Right now, she is helping to lift furniture into the van which will take our possessions to Ekalaka, where living is cheaper!

In the last two years plus, we have continued to use DMSO for—well, practically every ache and ailment. I am so "full" of arthritis that local M.D.s wonder how I can move. DMSO keeps me moving—pain-free—without any trouble.

I have a friend, Don Falk, who works 6 months a year for the Bozeman District Forest Service, U.S.F.S. But from October to April, he is in Arizona because arthritis keeps him in terrible pain during the winter months. Last fall, I gave him a bottle of DMSO. Now he runs around the forests like a young Billy Goat—without any pain!

I've used it on serious cuts and they have always healed in less than half the time it use to take! I've used DMSO on a sprained ankle and saved a doctor bill, and being off my feet for a week. I've used it on burns. For our physical well-being, the worst blow that could come to us would be to find out we could no longer get DMSO—and we even keep our horses healthy ("healthy as a horse!") and heal their wire cuts in 3 to 4 days with DMSO.

Because of DMSO we have almost eliminated our medical bills and we are so thankful for that. . . . Yes, I am trying not to ask the government what it can do for me—but, most of all, I hope it won't take our DMSO away! Rather, make it more easily available.

Very sincerely,

A. O. WENDELBURG.

ROCK ISLAND, WASH., *March 26, 1980.*

DEAR MR. PEPPER: My daughter Bronwyn has been on DMSO for 8 months, since she was 10 months old. She is 18 months. She is Trisimy 21 Down Syndrome which is the one that has the most severe problems in Downs.

Enclosed are height and weight charts. (Retained in committee files.) Bronwyn has been very slow to gain weight. The Doctor did several tests to see if there was a medical reason but none was discovered. She was a frail tiny girl. You will notice that her weight started to go up right after she was put on DMSO. She seemed to have more interest in food and ate a little more but was basically nursing until she was a year old so we're convinced the DMSO helped her.

We and other people around us noticed an increased awareness of people and objects around Bronwyn. She started taking a real interest in reaching out and touching things.

Bronwyn at 18 months crawls, sits up and pulls to a standing position, gets into my cupboards, is starting to feed herself and holds her glass well. She is an alert, cheerful little girl that we really enjoy and love. We are so pleased to have Bronwyn on DMSO and hope it will be available to others soon.

Sincerely,

DOROTHY NASH.

LAKE OSWEGO, OREG., *March 27, 1980.*

Hon. CLAUDE PEPPER,
Chairman, House Select Committee on Aging,
U.S. House of Representatives, Washington, D.C.

DEAR CONGRESSMAN PEPPER: After viewing the Mike Wallace "Sixty Minutes Show" on CBS last week in which the subject of DMSO was covered, I cannot refrain from writing directly to you as an influential member of our representatives who are considering the question of releasing this miracle drug to the public.

I am a senior citizen, semi-retired, but active. I play golf and travel extensively, and am currently traveling between Portland, Oregon and Uruguay as a Volunteer Executive for the International Service Corps.

If it had not been possible for me to procure and use DMSO, I would find it impossible to maintain an active productive schedule of activities that would ordinarily be taxing to my physical capabilities even during the years of my prime.

The responsibilities of The Federal Drug Administration are great, and the consequences of their actions must be considered with thorough research. Yet there are

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some things that should have higher priorities than others. Aging does not wait for such ponderous proceedings.

Respectfully yours,

FRANK KING.

SEATTLE, WASH., *March 27, 1980.*

Hon. CLAUDE PEPPER,
Chairman, House Select Committee on Aging,
U.S. House of Representatives, Washington, D.C.

DEAR MR. PEPPER: Concerning D.M.S.O., which is a substance you are studying for release to the general public. I am most concerned. My neighbor has to go to Oregon to get relief for her failing knee-caps. She has had some injections, also the salve, and finds it most helpful. Her friend goes with her and has had some treatment, and finds relief from her arthritis. They are both conservative people, and would not want something dangerous to be allowed, but in all their reading they do not find D.M.S.O. to be dangerous, and we feel that anything that can give such relief should be available to all.

I sincerely hope your committee will look at the facts and give an o.k. to this wonderful product.

Yours truly,

JEAN MCLELLAN.

LAKE OSWEGO, OREG., *March 27, 1980.*

Hon. CLAUDE PEPPER,
House Office Building No. 2,
Washington, D.C.

DEAR SIR: As I understand, your committee on aging is continuing its investigation of DMSO, especially as it deals with the easing of pain and stiffness connected with arthritis, but also it affects other human ailments.

I have been using DMSO both topically and by injection since mid-January of this year. Two and a half years ago I underwent spinal surgery for the relief of pinched nerves that brought on veritable paralysis of two fingers on my right hand. The surgery was, technically, superior; but it has led to regeneration of the deadened nerves. As a last resort, I went this past January to consult Dr. Jacob at the University of Oregon Health Sciences Center, inquiring about the use of DMSO for the nerve problem and for an arthritic problem I have had in my left hand for a long time. I have had considerable improvement with my left hand: the pain has almost gone entirely and the stiffness is definitely improved. Injections for the hoped-for regeneration of the nerves affecting my right hand have not so far brought the desired results. But I am still hopeful. Enough that the arthritis has been relieved to a very great extent.

I have known others who have had complete relief from their suffering from arthritis. One man, distantly related by family connections and one still quite young, wakened every morning with his hands tightly curled shut from arthritis. He sought Dr. Jacob's help, took the treatments of DMSO, and is now totally relieved—is, in fact, quite active physically, as he was in his early years.

It seems to me that your committee should recommend that FDA be directed to test and approve DMSO immediately, that the evidence already collected warrants approval, that side effects are minimal (I have had none whatsoever), and that those presently suffering should be given the same opportunity for relief as people who live in European and South American countries, where DMSO is freely used.

The FDA has taken an unconscionably long time in coming to any review of the use of DMSO (fourteen years). It will not do simply to argue that DMSO may have side effects still known or not yet experienced. Many drugs now on the active market have serious side effects; the widely used and usually helpful *penicillin*, for example—some people are seriously allergic to it; clinoril, widely used for arthritis, has been found to produce bad side effects seven months after it has been used; *atromid-S*, a drug used to reduce cholesterol, may be taken off the market because of serious side effects; even simple *aspirin* can aggravate an ulcer condition or give the user a stomach problem.

You and your committee can do a great deal to promote the approval for DMSO. I hope that you will act with vigor in seeing that the FDA takes action on its use.

Respectfully yours,

HOYT C. FRANCHERE.

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PORTLAND, OREG., *March 27, 1980.*

Hon. CLAUDE PEPPER,
Chairman, House Committee on Aging,
House of Representatives, Washington, D.C.

DEAR CONGRESSMAN PEPPER: I urge that you use your influence to make it possible for us, we the people, to make it possible to purchase this wonder drug, DMSO, for our miseries.

I personally, have been relieved from the pain of bursitis in the shoulder, tendonitis in a leg, the complete disappearance of some corns and a callus on my foot.

It seems we should be able to purchase this wonder drug without having to pay boot-leg prices, as we do now when we are lucky.

Thanking you, I am

Mrs. RALPH SOWERS.

WILSONVILLE, OREG., *March 27, 1980.*

HON. CLAUDE PEPPER,
House Select Committee on Aging,
U.S. House of Representatives, Washington, D.C.

DEAR SIR: My husband was injured in a automobile accident, April 1976. He had lamectomy on his cervical spine in Oct. 1976. Further surgery was to follow to correct a compression fracture in his mid spine. However, he suffered a heart attack immediately after the original surgery and the doctors felt he was too high a risk for further surgery—he has been in constant pain and many complications have arisen—i.e. gout, arthritis, hypertension, lung disorder & kidney problems—also a semi paralysis of the r. arm.

We were *fortunate* enough to be able to meet with *Dr. Jacob* and my husband has become a regular patient. *D.M.S.O.* has helped *relieve pain* & make it become bearable to get thru each day—the paralysis in his right arm & fingers is much less—his blood pressure is more stable—much because of the lessening of tension from severe pain.

We cannot say enough about Dr. Jacob's work—his staff & the caring—please help all you can to make the miracle available to all. We need your help so D.M.S.O. can help.

Thank you, sincerely

PAT L. BROOKS
JOHN W. BROOKS.

SILVER LAKE, WASH., *March 27, 1980.*

Honorable CHAIRMAN: We are pleased with your handling the hearing on DMSO.

I would like to testify to my experience with DMSO.

Several years ago I got a terrible case of tendonitis.

For 3½ years it has been with me interfering with *all* my work. Last year I got some DMSO for my horse.

I wanted to use it on myself but was afraid to use it and I didn't know how either.

I finally heard of the program at Portland.

They gave me a shot of DMSO in the sore part of my arm also some to rub, topically. The *1st* day I could lift my arm 10 inches higher than usual. In 3 days I can lift it straight up—no pain. No bad side effects—just the odor of DMSO. I am now able to drive, write, clinch a saddle, handle bales of hay to feed cattle, no pain—no hot pad. *This is real* not mental.

One day I burned my hand so badly it *instantly* started to blister. I applied DMSO on it. The *hurt* and *blistering stopped instantly.* I don't heal fast as a rule but when I cut my finger badly again DMSO worked wonders.

In my line of work I get bruised a lot and have blue marks for weeks. I received an extra bad bump one day and applied DMSO.

Again it was amazing. No sore area resulted, also no black and blue marks either.

I'm 52 years old and, like my mother, I've been getting *mole like growths* on my neck (where a necklace would hang). While rubbing the area for my shoulder problem, I rubbed DMSO on some of the growths, they have reduced over ⅔ in size and a growth that had just emerged has *completely disappeared.*

This is my personal experience, most of which I've documented in my day book.

I got to meet a paralyzed boy about Christmas time.

I could hardly believe the change in him when I saw him 3 weeks ago. He's being treated with DMSO.

I believe the DMSO should be in every household medicine chest.

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More importantly, DMSO should be a *Mandatory Supply* in all emergency vehicles and para-medics trained to use it in accident cases. I've no doubt it would *save many* people from life as a cripple.

Trusting you will do all you can to legalize DMSO for the benefit of mankind.

BENETTA M. BAKER.

HILLSBORO, OREG., *March 27, 1980.*

DEAR CONGRESSMAN PEPPER: I have used DMSO since about 1965, for arthritis of the back. The type I have is chronic inflamation of the disc. I've had 4 disc removed, 2 in lower lumbar and 2 in neck. Anyway, in 1965 I was in a car accident and in a wheelchair when I met Stan and was put on DMSO.

I am also an insulin diabetic and when a diabetic has pain, the blood sugar goes up and DMSO stops the pain and the blood sugar stays normal.

I am 46 now and I can get around, drive to the store. I can't lift or do much, but at least I am without pain most of the time, which makes it easier for my family to live with me.

I have not had any side effects, except I do know without pain I can live without being depressed. DMSO doesn't cure my problem but without pain helps me to get along. I am also on Clinoril 200 mg twice a day. I've got 15 thousand dollars in back surgery to date, each year another disc goes, without DMSO I wouldn't want to live. Please help others to be without pain, and let DMSO get on the market for others to use. . . .

Thank you,

MRS. SYLVIA WEST.

MOLALLA, OREG., *March 27, 1980.*

CONGRESSMAN PEPPER: I am in favor of DMSO. I have arthritis in my back and I truly believe without the use of DMSO I wouldn't be able to do very much as it does relieve my pain. I also use it on my feet when they ache and it helps ease the pain so I can sleep.

I have to tell a fib to buy it and my poor horse gets blamed for more than I use on him. I've been using it for about 6 years.

Sincerely,

Mrs. A. TAGGART.

BEAVERTON, OREG., *March 27, 1980.*

DEAR MR. PEPPER: Our family urges the committee on aging to recommend to the FDA that they release DMSO to the public.

We have used DMSO for burns, sprained ankles, sore and/or stiff joints, etc. for years. It is a shame to have to ration and, yes, hoard DMSO like we have. We are down to one inch left in the bottle and dislike going to the vet to get our "lame horse" some DMSO.

We know that it can relieve the pain for thousands of elderly—and young people. Let's not let them suffer any longer!

Sincerely yours,

Mr. and Mrs. FRED PRICE.

LAKE OSWEGO, OREG., *March 27, 1980.*

DEAR SIR: DMSO has helped me a great deal. I have bursitis in both shoulders and the pain is relieved in a matter of minutes when I apply this solution.

I hope that your committee will make it available, there are so many people who would benefit from it.

Yours truly,

KATHLEEN CRANSHAW.

TACOMA, WASH., *March 27, 1980.*

DEAR MR. PEPPER: This substance, commonly referred to as DMSO, was discussed last Sunday evening on the TV program "60 Minutes." It is a substance which has been used by a friend of mine, Mr. T., a quadraplegic, for the last several years. It was used by Mr. T. under the direction of Dr. Stanley Jacob of the University of Oregon. During the TV program, it showed many of the different ways it could be

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used and one of those ways was to remove pain from someone suffering from arthritis. For several years my shoulders have ached, especially at night and thus it has deprived me of many hours of sleep. After watching the TV program, I decided to ask my friend for a small quantity of DMSO which I then applied topically to the area that aches. To my joy, I slept better the first night so of course I repeated it the next couple nights and found that it continued to improve. Whereas I had usually tossed and turned all night long trying to find a comfortable position, last night, I turned over only once. Waking up this morning was a real pleasure because I was well rested. Being well rested hasn't been something I have been able to enjoy for a long time.

When I think of all the people who might be able to rest better and be more active physically if this were a drug that was approved by the FDA, I must encourage you to consider making this possible. It may be something that you could enjoy using if it were readily available.

It is now available in Oregon and Florida but I would hope it would soon be available throughout the nation. This can come about with your help.

Thank you for giving this your consideration.

Sincerely,

Pastor EUGENE ANDERSON.

DEER PARK, WASH., *March 28, 1980.*

Hon. CLAUDE PEPPER,
Chairman,
U.S. House of Representatives, Washington, D.C.

DEAR MR. PEPPER: I am writing to you in regards of the DMSO coverage. I was very pleased with the way the hearing was announced.

I have been following the research of Dr. Stanley Jacob since September 15, 1979, when my brother was severely injured in a jeep accident and suffered a broken neck.

This drug known as DMSO (Dimethyl Sulfoxide) has helped my brother tremendously. He went to the hospital being told he would never be able to do anything or move any part of his body for the rest of his life. Because of the positioning of the break, he would never have any feeling below the neck.

I feel that this drug would be of great value to the United States if it was legalized in every state and allowed in emergency vehicles instead of ONLY in Florida and Oregon.

Because of DMSO being administered to my brother, he now has movement in his arms and upper part of his body. He is now feeding himself, brushing his teeth, combing his hair, shaving himself, partially dressing himself, bathing himself and learning how to maneuver his manual wheelchair. I honestly feel that if Bill (my brother) had not had the opportunity to experiment with DMSO he would still be confined to his hospital bed. At the very beginning they told him to expect to be in the hospital at least a year if not longer. It is now six (6) months later and my brother is back home with our family in Toutle.

At the time of Bill's accident there were two other people in the hospital also using the drug, DMSO. Jenny, also breaking her neck, was told she would never walk again. Today Jenny is walking with a walker and is home with her husband. Terry Dean, a little boy with a massive blood clot in his head was not expected to live through the night. Terry was administered DMSO and was operated on that night. He is now home with his family. Lynn, another example of the drug. Lynn was raped and beaten very badly and was considered a vegetable if she lived. Because of the DMSO treatments she is also home with her family today.

Dr. Jacob has worked very hard with the drug DMSO to try and get it approved. I know Dr. Jacob personally and I honestly believe he would not be pushing for the drug to be legalized so dramatically if he did not feel it really was an asset to our country.

I hope and pray you will take this letter into consideration before making your final decision. If I can be of any more help or understanding in this matter, please feel free to call me any time during the week at my office in Spokane, Washington. My phone number at work is 1-509-328-5233. My working hours are 8:00 AM to 5:00 PM, our time. My home phone number is 1-509-276-5163.

Thank you very much for your time and co-operation in this very important matter.

Very truly yours,

TINA L. SHAAL.

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KRESS INDEPENDENT SCHOOL DISTRICT,
Kress, Tex., March 28, 1980.

Hon. CLAUDE PEPPER,
House Office Building.,
Washington, D.C.

DEAR SIR: It has come to my attention that you are Chairman of the House Committee on Aging. I urge you to make DMSO available to all Doctors who wish to use it. Since Dr. Jacobs was featured on 60 Minutes it has been quite a sensation in this little community.

The reason I know so much about it is that my son in Phoenix, Arizona was in an accident on July 3, 1977. He lived and is quite healthy with the exception he is a quadreplegic. He took his first series of treatments Feb. 10 of this year. The results so far is he is rapidly gaining some use in his left hand and he has regained the use of his tricep muscles. DMSO does not give anything but makes the availability of some of the nerves which control body functions. As I stated above the use of his triceps, he has to exercise and build them up to usable strength but he is doing that daily.

If you care to verify these statements you may feel free to contact Sen. Barry Goldwater or Sen. John Tower. They are knowledgeable concerning me and my son's accident.

Very truly yours,

EUAL V. BURTON.

PORTLAND, OREG., *March 26, 1980.*

Hon. CLAUDE PEPPER,
Chairman, House Select Committee on Aging,
U.S. House of Representatives, Washingon, D.C.

YOUR HONOR: It is indeed a pleasure to be in correspondence with you relative to your House Select Committee on Aging and the release of Dr. Stanley Jacob's drug, DMSO, for the treatment of many aches and ailments. It is good to see this investigation in your hands, for I have followed you many years as a U.S. Senator from Florida, and feel that you will give Dr. Stanley Jacob and his astonishing drug, DMSO, the fair and just inspection it deserves.

If you could have conversation with, and see, random patients (from every walk of life) that visit Dr. Stanley Jacob in his offices at the University of Oregon Medical School here in Portland, it would reveal the far-reaching applications of DMSO—with complete acceptance by each patient—in greatly helping or completely healing otherwise impossible medical situations. I AM ONE OF THESE PATIENTS; one who is completely healed. My problem was with an ulceration remaining on my right foot after several surgeries three years ago. There was just nothing that many doctors did that would heal this ulceration—until one day—the day last November that Dr. Stanley Jacob initiated clinical treatment for me, along with a well-defined home treatment program (with the use of DMSO) which I followed implicity. The results, over a short period of a few months, have been amazing, and I would testify in a complete, successful report before anyone.

It is time for the FDA to release, for public use, DMSO, for the relief of millions. Thank you for the expeditious handling of this matter.

Very truly yours,

WALTER GEORGE FERBAN.

MARCH 29, 1980.

Congressman CLAUDE PEPPER,
Representative of Florida,
Washington, D.C.

DEAR MR. PEPPER: An announcement was made, over the radio, for anyone wishing to submit info on DMSO to forward it to your office. As usual, the announcement was for those fast on shorthand and a flash recognition memory.

I consider my experience and knowledge of DMSO, its unsophisticated normal, simple use as equal to the best.

The following information will state how I became interested, how I used it, why and the outcome.

About 6 years ago, my ex-wife's mother had a heart attack. She was 82, her husband was 91. She recovered as well as could be expected under the age circumstance.

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When she returned home, her fingers began to painfully stiffen. She could not continue providing the wifely care for her husband, becoming completely dependent on him for dressing, cooking, etc.

When I learned of this my heart went out to her. I decided to apply my thinking that all problems have a solution, we may not always find the solution, but the solution is there, somewhere, one has to keep on trying—not give up.

I was aware of DMSO but never had reason to delve into it until now. I went up to the Dr. Jacob's DMSO clinic, read his book, talked to people who were using it and all, to get a handle on this stuff.

My ex had inherited a vericose vein problem in her legs. She had, in the past, had her legs "stripped", even so, the veins on the back of her legs were black. Her condition also gave her the "wiggly legs" every week or so.

The first experiment was to apply DMSO to the back of one leg where the veins were the darkest. The other leg was left alone for comparison.

I was amazed as I watched. In minutes, the darkest veins were turning a deep blue. Circulation was improving in minutes. Another result was that the "wiggly leg" condition did not reappear for three months with that one application. The other leg delayed for about a month.

About the same period, I was developing an "old age" muscle pain across the back of my shoulders. DMSO was applied. This skin was more sensitive, so that the characteristic "heat rash" and stinging appeared. I walked around the room, exersizing, to get it dried off. In 20 minutes it was dry and the irritation was completely gone. My muscular condition has never returned. It is now 4 years after.

Trail hiking—I severely sprained my ankle. DMSO, at the first opportunity, was applied to the swelled, painful ankle. Before the day was over, pain was gone, swelling subsided and what amazed me was that no dark discoloration resulted from the sprain.

As far as I was concerned now, the sky was the limit to reasonably and intelligently use this miracle medicine. I was not accepting it as a panacea.

Rubbing a wet finger across my gums to keep them healthy and tough is a daily practice. I tried DMSO, prepared for the worse to override the characteristic first phase irritation. No irritation developed and I could feel my gums tightening up to the point of being "squeeky clean", which didn't exist before. Just tried this once—had no need to continue it.

When I'm, occasionally, under high tension for a prolonged period, very moist eruptions appear on my face. I thought I'd check this out with DMSO. Using a Q-tip each "bump" was touched with DMSO. Minutes later I returned to the bathroom to wash up. After wetting my face I looked in the mirror. I was horrified at what I saw. My face looked like it was whip lashed, with red welts angling down, where the DMSO had run. For a moment I panicked and thought "My God, what have I done and how long will this take to clear up?" Then I cooled down, walked around to get it to air dry. In 30 minutes went back to take a fearful look, I couldn't believe it. Not a mark. Completely cleared. This time DMSO had no remedial affect as the condition returned later, unchanged.

Now, back to my ex's mother. We went down to California, now equipped to intelligently administer DMSO. Twice a day, upon her rising in the morning and just before her retiring, DMSO was applied to her fingers with an artist's camel hair brush. I instructed her to help the DMSO by exercising her fingers, to keep trying to close and open them each time of application.

The first week, nothing. Second and third weeks, nothing. I figured her condition was too advanced for improvement. Stayed with it though, with the exercising. 3½ weeks, a little improvement. End of the 4th week she could close her fingers. The 5th week she was picking up an iron skillet, dressing herself, etc., back to the independence and freedom she almost lost.

Some people I've talked with take the DMSO internally, one teaspoon in a glass of water. I haven't tried this—except what "went down" from my gum treatment.

DMSO, when diluted with water, heats up. I attribute this same effect when used on the more sensitive skin areas. The applied DMSO, full strength, combines with the more moist skin, producing what I compare with a heat rash break out. This dissapates in minutes on drying. This characteristic is one of the few prime points that the activist rejectionists latch on to to "prove" their point.

A girl friend subject to migraine headaches. I tried DMSO. Had her recline comfortably on a couch, applied DMSO lightly to her forehead. Had her rest, even take a short nap. Short time later she got up completely refreshed. She said this is the first time she ever experienced such comfortable relief. This is the basis for the medical rejectionists against DMSO. A product that cannot be patented represents a no profit venture. Patented products now on the market would be in jeopardy.

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Today I use DMSO on my "aging" joints, after a shower, every other day. Joints are kept limber—with exercise.

The die hard rejectionists, on any subject, will distort and fabricate the "facts" to back up their opposition, like our FDA.

As stated on 60 Minutes recently—a medical convention recently convened with representation on DMSO to present the subject—not a single one of these self chosen reps had ever experienced DMSO. So it goes with our own government.

DMSO is available on the encouraged black market for those who really want to go after it. The impure commercial brand is therefore also found with bad consequences and—again—which the rejectionists point to for their example.

It costs about 75¢ a gallon to produce and I paid $27 a pint and would have given more to get this extremely valuable aid. The government is in the exclusive position to use police state powers to protect and permit corporate control and profits, against the general betterment of the public interest.

Again, as indicated on 60 Minutes, the FDA would have approved the general use of DMSO long before now if the FDA was not influenced by the corporate medical lobbyists to keep DMSO off the open market.

I'll wager that a large number of our aging congressmen are using themselves this DMSO yet they prohibit its use by their constituents.

My definition of Progress, as it is today. First an about face, then "one giant step forward".

Sincerely yours,

JOSEPH B. RINDEIKIS.

PORTLAND OREG., *March 29, 1980.*

YOUR HONOR: I am writing this letter in regards to the Symms-Duncan legislation, which has recently investigated the DMSO issue.

I am a registered nurse presently employed in a hospital, and my job entails a lot of physical activity, including being on my feet most of a 8 hour day. About one and and a half years ago, I developed pain in my right hip. X-rays revealed no arthritic changes, only a mild scaleaits, which is a curvature of the spine, but no real evidence for the source of my pain or cause. I tried everything except pain killers, which I don't believe in using. I tried acupuncture, physical therapy, even used a new arthritic drug, Clinoril,which was of no help.

Finally, my doctor referred me to Dr. Stanley Jacob's research program on DMSO at the University of Oregon. I have undergone 7 treatments which has entailed injections of DMSO in the area of the pain, and at home, I apply topically the DMSO twice a day.

I have found that the pain and inflamation has decreased considerably to a point where I now no longer toss and turn, spending wakeful nights because of the pain. No longer do I wince in pain when some of the simple movements of making a bed used to bring tears in my eyes from the sharp, acute stabbing feeling I used to get while working at the hospital. All this relief I have received since I started using DMSO in the research program. I believe this product should be made available to the public, that the FDA should approve its use. You must have seen or are aware of the program "60 Minutes" aired March 23 on DMSO and the drug company official's indifference to DMSO, even if it was considered the wonder drug of the century. Are they afraid it might replace some of the schedule II narcotic pain medicine that so many people are addicted to in this country? I feel that the FDA should take note of these and other facts, and finally approve the use and prescribing of DMSO for public use.

Sincerely,

DIANE ABLE, R.N.

PORTLAND, OREG., *March 29, 1980.*

DEAR HONORABLE CHAIRMAN PEPPER: This letter is in regards of the drug DMSO.

Personal medical history: cancer operation at the University of Oregon Health Sciences Center in Portland, Oregon in 6/21/79, out 6/26/79, massive stroke, in 7/22/79, out 8/11/79. Complete paralysis left arm, partial left leg, extreme pain left shoulder, unable to do exercise because of pain.

November of 1979 first appointment with Dr. Stanley Jacob for treatment with DMSO. Treatments with DMSO weekly injections plus daily external applications. Result: loss of pain and some mobility. Resumption of exercise. . . . All medical records available through University of Oregon Health Sciences Center.

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Would sincerely recommend that you spend one day at said hospital to see how much this drug DMSO helps those that are ill.

Sincerely,

J. J. TERHAAR.

MARCH 30, 1980.

Hon. CLAUDE PEPPER,
Chairman, House Select Committee on Aging,
U.S. House of Representatives, Washington, D.C.

DEAR SIR: As a patient of Dr. Stanley Jacob at the University of Oregon Health Sciences Center, I can personally attest to the amazing results of DMSO.

I urge you to do everything in your power to achieve full approval of DMSO by the Food and Drug Administration as soon as possible.

Respectfully,

BOB HAWKINS.

CLACKAMAS, OREG., *March 30, 1980.*

DEAR SIR: I urge you to get the FDA to release DMSO.

I have used it and know of others that have used it. I have bursitis and arthritis and have had it for approximately 10 years. I had DMSO years ago, and it greatly relieved the pain. I would like to be able to go to my doctor or the drug store and get it.

Sincerely,

BETTY BROWN.

PORTLAND, OREG., *March 30, 1980.*

THE HONORABLE CLAUDE PEPPER: I am concerned with the issue of DMSO. I would like to see the use of DMSO easier to obtain. I have used it for a back injury and experienced immediate relief from the pains of muscle spasms. I feel it contributed immensely to my recovery. I have also used it for other various muscle strains and for chronic bursitis with favorable results.

I appreciate your interest and efforts in this matter.

Mrs. ROBERT J. STREICHER.

HILLSBORO, OREG., *March 30, 1980.*

SIR: Enclosed is an editorial, one of three from this area in the last week.

3,000 people had called Dr. Stanley Jacob's office two days after the "60 Minutes" program. Millions more are suffering pain ranging from acute to unbearable while the FDA sits and does nothing.

For 16 years people have been using DMSO bought from veterinarians or in more enlightened countries. No ill effects have been found.

I have used it for bursitis. It relieved the pain in two applications.

How long are you going to let the FDA be pressured by the drug companies to keep this off the market? Why are they allowed to sell all their supposed "pain relievers" which do not work and not sell the one that does? Must greed always triumph over human suffering?

Mrs. DONALD R. RUNDELL.

MARCH 31, 1980.

CONGRESSMAN CLAUDE PEPPER: I am writing in support of DMSO. I have personally known of the great relief from severe pain given to relatives and friends who have used DMSO.

The need to have DMSO on the open market readily available to the public is GREAT.

The American people need to have the opportunity to choose freely to buy this drug.

Sincerely,

HELEN STANKOVICH.
GEORGE STANKOVICH.

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BIDDEFORD, MAINE, *March 31, 1980.*

Hon. CLAUDE D. PEPPER,
House of Representatives,
Washington, D.C.

DEAR MR. PEPPER: I am writing in reference to the program 60 Min; last Sunday. Then last night I listened again and was so pleased to hear Mike Wallace mention your comment about DMSO that I just had to drop you a line and THANK YOU so much for myself and thousands of other Arthritis sufferers, it's gratifying to know that there is someone in office that has compassion for the human race, Bless You.

I am enclosing an article we had in the Journal after we came back from Mexico, it is self explanatory, it is now sixteen month's later and we do all our house work and feel just fine. I would recommend any one who need's help to please go they would never regret it.

Mr. Chafee did not like that, so he had an ad condemning DMSO, and I am enclosing MY ANSWER TO MR. CHAFEE, we haven't heard from him again.

It did not pass the Legislature this time. BUT Mr. Dutremble is going to submit the Bill again and with some one's help it will pass this time. If there is anything you can do to help again, we would ALL be most GRATEFUL, and (GOD BLESS YOU) for what you have already done. Thank you for taking time to read my letter.

Respectfully yours,

Mrs. ROBERT TARDIF.

PORTLAND, OREG., *March 31, 1980.*

Representative CLAUDE PEPPER,
Chairman, House Committee on Aging,
U.S. House of Representatives, Washington, D.C.

Representative ROBERT DUNCAN,
U.S. House of Representatives,
Washington, D.C.

DEAR CONGRESSMAN PEPPER AND DUNCAN: I totally support your position as to making DMSO available to the public in treatment of pain and approved related conditions. I along with friends and clients have used DMSO and the majority of us have experienced some relief of pain in treatment thereof. I fail to understand the attitude of the FDA in withholding the availability of DMSO to the public. In my opinion, the FDA has failed to give a rational common sense explanation why DMSO has not been approved for use to the public.

I am in total support of Congress passing legislation authorizing the use of DMSO in treatment of particular medical conditions in the event the FDA fails to take prompt action on granting approval.

Thanks for your sincere interest on behalf of the public.

Sincerely,

RICHARD L. AMATO, P.C.

GRESHAM, OREG., *March 31, 1980.*

Mr. CLAUDE PEPPER: I am writing for the use of DMSO being put on the market.

My mother is a victim of crippling arthritis. She was given some DMSO to use on her hands. She now has the use of her hands and her fingers due to this product.

Please, for the benefit of all arthritic people and the many other illnesses that it has and can help, please help put it on the market for all.

Thank you,

HELEN WOHLSCHLEGAL.

PORTLAND, OREG., *March 31, 1980.*

DEAR MR. PEPPER: My mother, Ruby P. was one of the first "guinea pigs" for DMSO through Dr. Jacob. When she first started she had both legs wrapped in ace bandages and used 2 canes. Her hands were so gnarled she couldn't close them.

She is now 85 years old, makes quilts in the winter, does her own housework, spades up her own garden and tends it and mows her own lawn.

As a matter of fact, for the last three years she has ridden her three-wheeled bicycle about a mile down to my house and spade and tended by garden also.

She not only applies DMSO externally, but also drinks it. As for side-effects, I must say her breath wasn't very nice (this is not the case anymore) but this was a very small price to pay for the health it has given her.

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So much for that.

I had gout in both knees, arthritis in hands, wrists, shoulders and neck. The doctors called in a "shrink" to tell me I would not walk again. He told me to get a motorized wheel chair.

That was in 1977. In 1978 I got diabetes and mother persuaded Dr. Jacob to accept me as a patient in March of 1979.

To make a long story short—I not only walk, I do my own gardening and drive my car again—in one year—with external applications of DMSO.

I got neuritis in my right arm and a lump on my finger and Dr. Jacob shot the DMSO in my shoulder and in 5 weeks there was no pain at all.

DMSO helps clear up small wounds which are difficult for a diabetic to heal—and no scars. Most of all it has given me a new life!

Side effects? One. I had very grey hair (I loved it) but in the past year it is coming in red again—and curly (it was straight before). Hardly something to complain about!

I do hope you can do something to the FDA to release it so others can have a new life too. When I think of the pain other arthritics are having just because of the FDA—I really get mad!

If you need more details, please me know.

Thank you,

Mrs. R. F. BAXTER.

BELLEVUE, WASH., *April 1, 1980.*

Hon. CLAUDE PEPPER,
House Select Committee on Aging,
Washington, D.C.

DEAR REPRESENTATIVE PEPPER: I want to urge you and your Committee to release the drug DMSO.

I have used DMSO myself and it has worked in the relief of the arthritic pain in my knees. The only side affect is the odor of oysters for a day or two following a topical application. I use DMSO because other drugs have proven ineffective (cortisone, butizolodin), and a surgical technique suggested by my doctor would require that my legs be immobilized for a period of six months with a 50 percent chance of improving my condition.

DMSO works for me, I know it has worked for other people. Please do what you can to get it out of the bureaucratic quagmire of the FDA.

Sincerely yours,

RICHARD L. BAKER.

THE FARMERS INSURANCE GROUP OF COMPANIES,
SEATTLE, WASH., *April 1, 1980.*

Hon. CLAUDE PEPPER,
House Select Committee on Aging,
Washington, D.C.

DEAR SENATOR PEPPER: On Saturday March 29, 1980 I was able to locate a small quantity of DMSO, which I immediately began using on a shoulder which was quickly becoming frozen and with muscle deterioration beginning. I began with bursitus a year ago, and at the end of the year, and after cortisone shots directly into the shoulder, and many, many aspirins as well as other anti-inflammatory agents, it has grown progressively worse.

I have a very capable doctor, who I trust, but her hands are tied. She can only prescribe that which is available to her, by law. I have advised her that I located some DMSO.

As of the moment, my shoulder is pain free, and I am beginning to get some movement in my arm, that was not able to make on Saturday morning when I woke up. I have only taken two aspirins since Saturday. I am not healed yet, but I know that I am on the way to being cured. The medical folks have been telling me, that because I was fifty years old, I was just going to have to learn to live with these kinds of infirmities, for the rest of my life. Somehow, I just can't believe that God would intend to keep us alive just so that we can suffer, but it does appear as though the medical, pharmaceutical, and governmental folks would like us to think so.

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I feel the government should get out of the medical and drug business. If any drug can help people, why should the government say no. The government is supposed to govern, not administer to the health of the body.

Thank you,

NAIDA CARLSON.

PORTLAND, OREG., *April 1, 1980.*

DEAR CONGRESSMAN: I have been using DMSO for several years now. I am 52 years old, my husband is 54 years old. He uses it off and on, too. I use it on cuts, bruises, and if a blister starts on my foot, I put it on there and it is usually dried up in a couple of days. I have used it on soreness of the muscles, especially on my shoulders, for tension. I have been able to get it from one doctor. But if I can't, I get it other ways.

You hear of so many ways it helps different ailments, especially in older people for bursitis, arthritis, and so on. Yes, it has an odor but what's that if it helps. Some people do have an irritation to the skin but that won't happen it you dilute your DMSO with water and apply mineral oil or a lotion before applying the DMSO. I have a close friend who has osteoarthritis. She's under a doctor's care and they give her treatments using DMSO. She had to quit work, started treatments 2 to 3 times a week for sometime and down to once a week and now goes in every two weeks or how she feels. Course, she's not cured but does feel a lot better now.

Guess I could go on but just to share my views with you might be of help. I would like for it to be easier to get.

Thank you,

MRS. VIVIAN MCCAY.

CORBETT, OREG., *April 1, 1980.*

DEAR HONORABLE CLAUDE PEPPER: I am 55 years of age; have had arthritis, troubles since approximately 35 years old. Very mild compared to many sufferers yet I want you to know that DMSO has been a wonderful pain reliever for me time after time after time during the past 9 or 10 years. I was fortunate to get on Dr. Jacob's experimental list back in 1970. (It was shortly after that that the acceptance of additional people on this list nearly came to a "grinding" halt because Dr. Jacob could simply not handle them all).

For me DMSO has been a pain killer for arthritic problems (primarily hands), while also during this last 9 years I've had occasions to try it on sprained ankles and feet and wrists; my back several times after bad falls.

I'm convinced that it has been good for me. Perhaps it's because I'm an engineer that I was very suspicious initially. After all, there was no understanding of how DMSO worked (and I guess there still isn't). The only thing I'm sure of is that it has effected wonderful relief for me many many times.

I think it's terrible that it (DMSO) is not available to most everyone. Can't something be done about this?

Sincerely,

DAVID M. BELL.

PORTLAND, OREG., *April 2, 1980.*

Hon. CLAUDE PEPPER,
Chairman, House Select Committee on Aging,
U.S. House of Representatives, Washington, D.C.

DEAR MR. PEPPER: We, the undersigned, believe DMSO should be legalized without further ado, having benefited from its use for various ailments by ourselves, families or acquaintances, without any harmful side effects.

We feel this very effective drug should be made available to the public with no more time and tax dollars spent on bureaucratic red tape.

Very truly yours,

Betty Spohn, Lou Ann Cook, Eva Goff, Jerry Fuikurt, Lorrain Loggins, Gerald Stevens, Lurene Lange, Lois Davis, Patricia A. Wiley, Robert Chandler, Henry S. Stephens, Vera Cole, Alice Bryan, Sharon Brumbaugh.

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PORTLAND, OREG., *Wednesday, April 2, 1980.*

Hon. CLAUDE PEPPER,
House Select Committee on Aging,
U.S. House of Representatives, Washington, D.C.

DEAR SIR: I would like to take this opportunity to relate some personal experiences I have had with DMSO. I first became aware of DMSO in the summer of 1970. At that time my grandmother became one of Dr. Stanley Jacob's first patients for treatment of arthritis which was crippling her hands. Over a period of a few years her hands improved and the frequency in applying DMSO was gradually reduced until she no longer needed to use it. Today she is 92 and still has the use of her hands although she has not used DMSO, except on occasion, for the past 7 or 8 years.

I have continued to get DMSO, first for her use and then for my own use, over the years from the office of Dr. Jacob at the University of Oregon Health Sciences Center. At no point while using DMSO have I ever experienced any adverse side effects with the exception of odor on my breath and minor skin inflammation on occasion. The personal benefits have been very significant on a number of occasions. Five years ago I received a severe deep thigh bruise while playing basketball which was the identical injury that occurred to me 13 years earlier while participating in a high school basketball practice. At that time I was out of action for a period of 6 weeks although I applied various balms, utilized whirlpool baths, and underwent ultra-sound treatments. Following the occurence of that injury the second time I applied DMSO regularly for 7 days and at the end of that time I was able to play basketball with no adverse effects.

Three years ago I sustained a bad sprain while playing soccer. After packing the ankle in ice for 24 hrs, I put DMSO on it twice a day for 4 days and then once a day for 3 days. After a period of 10 days I was able to resume playing soccer on a full-time basis.

More recently I have been receiving injections in my left knee from Dr. Jacob. I have osteoarthritis in this knee which has been getting worse over the past two years. During the past year I underwent two arthoscopy operations in an attempt to eliminate "clicking" in my knee, as well as flushing it out. Following the second operation I began using 87-2 DMSO topically on a regular basis. Subsequent to this I started taking injections of 20 percent DMSO with xylocaine which were administered by Dr. Jacob. Although the "clicking" persists (another operation may be necessary) and there is no scientific basis for using DMSO, the swelling and associated pain have gone away. With the exception of activities involving running, I have full use of my knee whether walking, lifting, bicycling, or swimming.

The last example of the beneficial effect of DMSO involves my sister-in-law. She has scleroderma and her condition has been deteriorating the last two years. She has not been able to obtain any relief from physicians in the Seattle area. As a last resort she became a patient of Dr. Jacob. Although she has continual discomfort (pain and swelling) particularly in her wrists and ankles there has been considerable improvement in recent months.

I don't subscribe to the theory that DMSO is a miracle drug. However, because of the numerous instances where it has been of benefit without harmful side effects, its use can be justifiably increased. I believe the actions of your subcommittee are a good first step in this direction. It is my hope that the use of DMSO be maximized for society's benefit even if pharmaceutical companies don't stand to make a substantial profit.

Sincerely,

TERENCE M. BELLERBY.

FLORIDA HOUSE OF REPRESENTATIVES,
TALLAHASSEE, FLA., *April 3, 1980.*

Hon. CLAUDE PEPPER,
House of Representatives,
Miami, Fla.

DEAR CONGRESSMAN PEPPER: I was recently in a discussion with another legislator from Florida. He was aware that I, as a consumer, am familiar with the effects of dimethyl sulfoxide (DMSO).

The Florida Legislature enacted legislation in 1978 and 1979 which prohibits interference with the physician-patient relationship by restricting use of dimethyl sulfoxide. I agree strongly with this legislation. When the law is properly implimented, a medication giving substantial relief from pain of various origins will be available at a modest price to persons who would otherwise be unable to obtain the

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services. Dimethyl sulfoxide is effective against pain arising from such conditions as Rheumatoid Arthritis, sprains, Bursitis, pinched nerves, neuralgia, etc. . . .

I wish to express my support for your legislation making this medication available to the average citizen.

Respectfully,

ARNETT E. GIRARDEAU.

SCOTTSDALE, ARIZ., *April 3, 1980.*

Hon. CLAUDE PEPPER: Would you please use your influence to legalize DMSO? Our daughter broke her neck in an auto accident and for the first time in 6 years is pain free because of using DMSO

I have lived with chronic intractable pain for 12 years because a Dr. over-radiated me in the lumbosacral spine. But it is great for arthritis

We thank you for whatever you can do to legalize it in every State.

Sincerely,

Mrs. HAROLD DEAL.

POST FALLS, IDAHO, *April 4, 1980.*

Hon. CLAUDE PEPPER,
Chairman, House Select Committee on Aging,
Washington, D.C.

In regards to the D.M.S.O. bill which is now before you.

While in Oregon driving the week of March 23rd, we were able to obtain a small amount of D.M.S.O., and I would like you to know just how much it has helped both of us.

My husband Bill has suffered with arthritis of the knees for years, as a result of an airplane crash and surgery during World War 2, while serving with the U.S. Airforce. During this time he has tried many, many remedies short of artificial knee joints, with very little relief.

I have been effected only since last Christmas in the right thumb, and have not been able to lay the thumb in the center of my palm.

After applying a small amount of the D.M.S.O., we both noticed a big difference in a very short time. He was able to walk much better and I was able to freely move my thumb.

The trip from Portland, Oregon, to our home in Post Falls, Idaho, takes about seven hours. Every time we have made this trip his knees have been very painful for a few days. However this time he applied some D.M.S.O. before we left Portland and I did not hear one complaint about his knees during and after the trip, I also notice that he was walking much better.

I am not saying that either of us were completely free of pain, but it sure did deaden it, and were able to move our effected areas with very little pain.

We understand Steve Symms of the House of Representatives, is trying to get a bill passed permitting the general public to obtain D.M.S.O. for such use.

Please, I ask any of you who are effected such as we are, to get some and try it, before voting on this bill, or talk to some one who has used it.

D.M.S.O. is much better than living on asprin, which can be harmful, or having a surgery of an artificial joint, which does not always work. With D.M.S.O. we can at least live with our pain.

Thank you for reading this letter.

We remain,

Mr. and Mrs. W. E. HEDRICK.

BROKEN BOW, NEBR., *April 5, 1980.*

Hon. CLAUDE PEPPER,
House Select Committee on Aging,
U.S. House of Representatives, Washington, D.C.

SIR: I am a victim of the frightening disease, Scleroderma. I am extending my personal thank you for the effort you are putting forth for me and my fellow scleroderma friends.

I personally tried DMSO 2½ years ago while I was still a resident of California. A rheumatoid specialist obtained it for me from his own veterinarian. It was used on an ulcer on the ankle bone area. Later, after I ran out of DMSO I developed a staph infection. My contact with fellow scleroderma patients has assured me that DMSO

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works. My personal feeling is that DMSO should be made legal and available to scleroderma victims.

Due to a staph infection, I have had my right arm amputated just below the elbow. A direct result of scleroderma.

The baffling disease, scleroderma, causes its victims to seek help from any available source. Please continue with your assistance.

Most Sincerely,

MARIAN J. CAREY.
JENNIE MELHAM LONG TERM.

EAST WENATCHEE, WASH., *April 5, 1980.*

Hon. CLAUDE PEPPER,
Chairman, House Select Committee on Aging,
U.S. House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: Mrs. Dale Clark requested that I write to you regarding Melody Clark, an eight year old Downs student, who is taking DMSO.

Melody was transferred to the E.M.R. class in September, 1979 and has maintained a steady academic growth.

Because this is my first teaching experience with a Down's child and because my first-hand knowledge of Melody's performance has been limited to this school year, I am not qualified to attribute her progress to DMSO. However, in view of Melody's academic achievements, I would like to see DMSO given a fair testing and evaluation in helping the handicapped. If I can be of any further assistance, please contact me.

Sincerely yours,

ROSE MULLAN,
Special Education Teacher,
Sterling Middle School.

SALEM, OREG., *April 5, 1980.*

DEAR SIR: I am writing regarding DMSO. I am 75 years old, veteran and an R.N. I have a service connected back, 5 operations, plus 2 after my discharge on my back. I feel that after my spinal fusion in 1950, that I had excellent results, but in the last few years have had arthritis through my entire spine.

My doctor finally told me that there was just nothing left for him to do, to try DMSO. He did not tell me how or where I could get it. Tried veterinarians but had no dog, yes, I had no dog, so I couldn't get it. Finally found a kind gentleman who told me where I could get it.

Thanks to the Foundation in Portland, I was able to get it, and needless to say, I'm thankful. I won't say that it has cured any of my aching joints, but I've been able to stay on my feet, instead of in a wheelchair.

If there is anything that can ease arthritic pain, that effects so many older people, don't you think it should be given to them?

As far as I'm concerned, there has been no adverse effects. I can't say the same for aspirin and many other arthritic drugs.

By the way, I've used it internally and externally, it doesn't taste good but, in tomato juice, I don't mind it. As an act of charity to the millions of people afflicted with aches and pains, anything as effective yet harmless, should be allowed. Please, please use your influence to force FDA to okay this priceless remedy. I don't even consider it medicine or drug, just a remedy.

I picked up the handle of an iron skillet, out of a 450° oven. Grabbed the DMSO and poured it on. My hand got red, but little pain, no blisters.

Thank you for your consideration.

Sincerely,

GERTRUDE T. FOX.

ORMOND BEACH, FLA., *April 7, 1980.*

DEAR SIR: Please see what you can do to get DMSO made available for patients who need it. Our daughter needs to use it daily as she has Raynaud's disease and scleroderma.

She has been going to Gainesville now for about 5 years, a doctor up there sent her to a doctor in Brunswick, Georgia. She was put on the experimental program by the doctor and DMSO helped her. Gainesville is 115 miles and Brunswick is about 150 miles from where we live, and gas being the price it is, that is a distance to

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travel to get medicine she needs. Appreciate all the help you can give to get the bill passed.

Sincerely,

AGNES SCHENIDER.

JACKSON, MISS., *April 7, 1980.*

Congressman CLAUDE PEPPER,
Washington, D.C.

DEAR CONGRESSMAN PEPPER: It has been my privilege to receive DMSO for my Arthritis. It has stopped the pain. This means everything to me. It is not a cure—there is no cure at this time.

Since the Council on Aging has ruled favorable on DMSO also the Arthritis Foundation endorsed it as a pain reliever.

Will you contact Jimmy Carter, Our President and ask him to use his Executive Power to order the use of DMSO as a pain reliever. It has been used by Dr. Jacob, of Oregon for many years successful, also in Florida.

It would mean a great deal to Arthritis suffers to have a legal drug for pain.

Very truly,

Miss WARRENE SHAWHAN.

STERLING HEIGHTS, MICH., *April 7, 1980.*

Hon. CLAUDE PEPPER,
House of Representatives,
Washington, D.C.

I forward this communication to you as I understand you are discussing the properties and powers of DMSO (Dimethyl Sulphoxide).

I have used DMSO for all manners of sprains, muscle pulls, etc., and have found the curative powers of this chemical to be unbelievable. That is to say, relief from pain and recuperation have been immediate.

Anything that you can do to bring this product to the marketplace for the general use of the public, it would seem to me, would end untold human suffering.

Sincerely,

CRAIG D. BECKER.

YAKIMA, WASH., *April 7, 1980.*

Hon. CLAUDE PEPPER,
House Office Building,
Washington, D.C.

DEAR REPRESENTATIVE PEPPER: I read with interest an article in today's paper about your testimony before the House Select Committee on Aging during a congressional hearing in Washington, D.C. last month. Thank God we do have a few people in Congress with brains enough to stand up for the discomforts of the aging.

Enclosed you will find an article from our local paper which gives the testimony of a Mr. Irvin Lysle. I happen to know Mr. Lysle personally and can remember when he was so troubled with the bursitis. I knew the people he worked with and they still tell of how much pain he was in. He is just fine now and has been ever since the treatment and has done much good for the Yakima Valley since his cure.

About two weeks ago I had my first treatment with DMSO for interstitial cystitis. This is a perfectly miserable condition of the bladder with very little that can be done for it until DMSO came along. It has been considered not curable. I have had it for several years and had to have the bladder physically stretched under a spinal block. It is an inflammatory disease and is most painful. I am just amazed at how fast the DMSO worked. I had no side effects that I could detect. I did not have the bad taste in my mouth, though my husband said that he could smell it on me for a few hours. I do not know of any other medicine, drug or anything else that can give such wonderful relief from real pain with so minor a side effect.

I also suffer from bursitis and would hope that something can be done to wake up the FDA officials. If you would give me names and address, I would be more than happy to write them if you think it would do one iota of good. They are so stuped in so many respects. Every drug on the market has some side effects for some people that are many times more serious than a bad taste in the mouth for a few hours. I probably can get some DMSO illegally, but I would much prefer to get it legally and have it administered by a doctor.

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If I can be any assistance to you, please let me know.

Sincerely,

Mrs. M. D. KOLIHA.

P.S.: Keep up the good work.

ONTARIO, CANADA, *April 8, 1980.*

DEAR MR. PEPPER: Inclosed you'll find a copy of a letter that I sent to Mike Wallace after viewing 60 Minutes March 23.

Bless you, you are like the light at the end of a dark tunnel. We people who have lived with D.M.S.O. and reaped it's benefits seemed to be fighting a losing battle. With Rep. D. Bonker's and your help, perhaps we can finally be heard. We have never met a more dedicated person than Dr. S. Jacob.

Keep up your great work and if we can be of any help just let us know.

Thank you, thank you,

Sincerely,

Mr. and Mrs. HAROLD SAVAGE.

MARCH 24, 1980.

DEAR MIKE WALLACE: Bravo on your story of Dr. Jacob and D.M.S.O. 60 Minutes, what took you so long? About 5 years ago in Portland your film crew taped our son's and other success stories of D.M.S.O. It was never shown.

Our son had been in a coma due to an auto accident. After 6 months in the hospital we brought him home. His Drs. said that he would probably never regain bladder control. In 1973 he became a patient of Dr. Jacob. Within months of using D.M.S.O. he had full bladder control.

Our hometown of Ontario, Ca. can attest to the many great changes it has created in Randy's life.

The F.D.A. says to test it more . . . . More? If Salk vaccine had been tested as much, we still wouldn't have it.

The F.D.A. and big drug companies be damned . . . Their greed for money has caused enough pain in our world.

Sincerely,

Mrs. H. L. SAVAGE.

ARTESIA, N.MEX., *April 9, 1980.*

I am writing to you concerning the Symms-Duncan Legislation. I want to congratulate you on what you are trying to do for people like myself. I have Scleroderma and would like to tell you a little about myself; so you can see how much this legislation means to me and to others who have this terrible disease.

I was 25 years old with a five year old daughter when I was told I have Schleroderma, and that there is no cure and very little help for it. About the first 13 years, it wasn't too bad. I had ulcers on my fingertips. I only had pain while the ulcers were healing, and being cold during the winter months.

But the last six years have been something else. In 1974, I had an amputation of my first toe. And then in 1979, I lost two more. I am enclosing some pictures so you can get an idea of what has happened to me.

The last five years, during the winter months, the only way to get by is to live on pain pills and then it doesn't do the job just takes the edge off. You lose weight and walk the floor at night, because you can't sleep for the pain. The pain is with you day after day til you don't think you can take it any more.

Then the first part of 1979, I started having chest pains and trouble with my lungs. I couldn't even clean up one room without sitting down and resting. I've always been able to take care of myself. And it's very hard for me to have to accept help from others. Another thing about this disease is you can't get health insurance or if they will, it's so high you can't afford it.

That's the bad side of Scleroderma. Now for the good part, the only ray of hope I've had in 19 years. I went to Portland, Oregon to see Dr. Jacob last July. He started me on a treatment with DMSO. After the first week, I felt better than I had in 19 years. I could button my own clothes, reach behind my head. The pain was almost nothing. Four months later I no longer had chest pains.

I have just come through one more winter and it's the best winter I've had in six years. I had a few bad points where the pain was pretty rough, but they didn't last long. Now when I get ulcers I use DMSO and it clears them up. Also, I didn't have anymore amputations. I feel that I owe my life to DMSO and to the work that Dr. Jacob has done. I feel that now I might have a chance to see my children grown and to be able to enjoy my grandchildren.

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Please help us, we need you to help us fight for a better, pain free life.

Cordially,

LILLIE FORISTER.

WENATCHEE, WASH., *April 9, 1980.*

Hon. CLAUDE PEPPER,
Chairman, House Select Committee on Aging,
U.S. House of Representatives, Washington, D.C.

DEAR SIR: I am writing to you in regards to DMSO. The miracle healing substance of today. I do not consider DMSO a drug.

It has been my pleasure to see a Down's Syndrome child by the name of Melody Clark, make exceptional progress from practically a vegetable state of existence. If you and your Committee could see this child in action, I am certain you would be impressed and humbled by the experience.

I am also aware of how DMSO can help arthritis, shingles, burns, and severe traumatic injuries with no noticeable side effects. The program "60 Minutes" was in fact tremendous. I feel that Dr. Jacob of the University of Oregon's Medical School, should receive a *special* commendation for his tremendous service, dedication, and willingness to buck opposition as he knows the true merit of DMSO.

I hope that your Committee will make it possible to legalize DMSO so that it can be available to those who need it, benefit from it, and choose to use it. I am also aware of the pressure the American Medical Association can put on your Committee. I hope you will listen, search out those who have been helped, and take these facts into consideration.

If I can be of any help in my area of Washington State, please feel free to call me (509) 662-6474.

I would like to express my thanks and appreciation for the work your Committee has done. May you give a favorable recommendation to the Federal Drug Administration to release for use—DMSO.

With mutual interest and support,

CHARLOTTE THOMPSON, Ph. D.

PORTLAND, OREG., *April 9, 1980.*

Hon. CLAUDE PEPPER,
U.S. House of Representatives,
Washington, D.C.

DEAR CONGRESSMAN PEPPER: I have been employed at the University of Oregon Health Services Center where Stanley Jacob is a faculty physician for over five years. I have used DMSO for four out of the five years I have been employed at the Health Science Center. I have used it for a severe knee sprain, cooking burns, a severe strepth virus to relieve throat pain and for acute arthritis flare-ups in the neck and in my knee. In all instances, DMSO has proven to be most effective.

I wish to congratulate you on holding the hearings on DMSO at long last! I sincerely hope that DMSO will soon be freed for general use particularly for arthritis since on an experimental basis, it is most effective for a large segment of the population who have already tried it on an experimental basis.

Yours sincerely,

Miss JACQUELINE H. STAVEN.

PHOENIX, ARIZ., *April 10, 1980.*

Hon. CLAUDE PEPPER,
Chairman, House Select Committee on Aging,
U.S. House of Representatives, Washington, D.C.

DEAR HON. CLAUDE PEPPER: I am a quadraplegic as a result of a C5–C6 spinal injury, which happened July 3, 1977. I have no use of my legs and limited use of my arms and hands.

February, 1980, I went to see Dr. Jacob in Portland for DMSO. I have had no negative side effects from the drug. I have had some sensation return in the upper part of my legs. In my situation, any return at all is a gift.

Dr. Jacob's DMSO gives us hope. People have suffered long enough. We can't all go to Portland. DMSO should be available in all states.

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Thank you for your attention.
Sincerely yours,

DENNIS E. BURTON.

FLOWERY BRANCH, GA., *April 10, 1980.*

DEAR HON. CLAUDE PEPPER: I want to congratulate you on what you are doing to help the scleroderma program.

I am writing you because I have scleroderma and I can tell you it's very painful though you hurt so long you learn to live with it. Before I started using DMSO I was swollen and lots of fluid, and my fingers begin to drain, then ulcers come on my hands. And I couldn't lift anything, couldn't hold things in my hands very well.

They started me on DMSO and I got better and was beginning to use my hands better, fluid and swelling was gone. I sure hope I can get more.

Since I got out I was getting more ulcers on my fingers and hands, swelling back up. Before I use DMSO I lay and cry at night I hurt so. I hope and pray I don't have to go through with that again.

I want to thank you again for what you are doing to help.

Sincerely,

Mrs. BROADUS CRANE.

SELAH, WASH., *April 11, 1980.*

TO WHOM IT MAY CONCERN: I have read a great deal about DMSO and have also used it and seen it used. The relief my mother-in-law received by the use of DMSO was fantistic. After years of surgery and drugs (approved), she applied DMSO and within a short time obtained relief from (all) pain. She has tic delaroux in which there is no cure, just pain and suffering. Even the prescribed approved drugs are of little value, especially with the side effects and possible overdose and addiction. I personally administered the DMSO and saw the relief she had. Thereafter she applied DMSO as needed for her pain and always got relief with no side effects. Now, out of DMSO and no place to get more she is back to be drugged and suffering.

Other drugs and ointments, etc. are on market with no fuss and all have side effects, so how can the F.D.A. set judgment of DMSO. We make our choice on many over counter drugs all with side effects so why keep DMSO out of reach when it can do so much good. I as many others believe DMSO should be allowed on the market to all people. The F.D.A. should forget how much money and political aspects they can receive and have more empathy for their fellow man. Let DMSO go, let it help the suffering and put a stop to the F.D.A.'s obsession to crucify the people involved with DMSO.

What are they afraid of a miracle or do they just like to make a big noise and cost taxpayers more by court cost, investigators, just plain busy work.

I vote for DMSO. Now. It is needed now not 100 years away.

People are suffering now let us help them to live free of all pain if possible.

Sincerely,

JOYCE LOUISE RATLIFF.

NORTEN, OREG., *April 12, 1980.*

DEAR REPRESENTATIVE PEPPER: I was glad to receive word from Mrs. Barlet, founder of the Scleroderma International Foundation, about the hearings which were held relating to the approval of DMSO by the FDA for the treatment of victims with scleroderma.

This issue came before the FDA last year about this time. I wrote letters to my Congressman and Senators urging them to make this issue known by contacting the FDA and voicing my opinion. I am now writing those same letters again this year.

I feel it necessary to briefly describe myself in order to put this issue into perspective. I was told I had scleroderma in 1973. I am twenty-nine and unable to work due to this disease. I was a Learning Disability's teacher.

Skin ulcers are characteristic of scleroderma. I have these ulcers on my fingers and elbows. They are extremely painful, and they take a long time to heal. I'm one of the lucky patients who uses DMSO. Before I had DMSO, I had ulcers which took 8 months to heal. I've been using DMSO on my skin ulcers since November, 1977. At the present time there is nothing a doctor can prescribe for scleroderma patients to use on their ulcers. I know through my experiences that DMSO works. DMSO helps heal the ulcers, relieves the pain that accompanies them, and softens the ulcer and the surrounding tissue. The pain which I have experienced from the

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ulcers can best be described as being comparable to a knife blade piercing the tissue beneath the skin. After applying DMSO to the ulcerated area, the pain is gone in a matter of seconds. DMSO has been effective in my case. I have had positive results. My only wish is that all scleroderma patients be given the chance to try DMSO for themselves. I hope you can now understand better what DMSO means to the scleroderma patient. Please remember that you and the committee will be speaking for many people. I truly appreciate your concern for this issue, and I hope your efforts are successful.

Sincerely,

CYNTHIA HONAKER.

PHOENIX, ARIZ., *April 13, 1980.*

Hon. CLAUDE PEPPER,
Chairman, House Select Committee on Aging,
U.S. House of Representatives, Washington, D.C.

DEAR HONORABLE PEPPER: I am a C-7 (incomplete) quadriplegic and am writing you regarding the use of DMSO. I saw the segment on 60 Minutes recently and it is my understanding that DMSO is now before the House Select Committee on Aging. I would like to offer you my experiences with DMSO.

In the latter part of December, 1979, I entered the University of Oregon Medical Center to receive DMSO under Dr. Stanley Jacob. In the four months that I have been taking DMSO, I have experienced no negative side affects. I have had numerous and various movements in my legs during this time that I never had before since my accident. Although they have been involuntary at this point, I feel that this is a good sign and hope to have more controlled return as time progresses. I feel very good, healthy and optimistic about my continued use of DMSO.

I am very grateful to Dr. Jacob for allowing me to become his patient and sincerely hope that the FDA will release DMSO for immediate use.

Sincerely,

JAMES L. WAGES.

HALLANDALE, FLA., *April 14, 1980.*

Hon. CLAUDE PEPPER,
Committee on Aging
Washington, D.C.

DEAR SIR: The DMSO controversy write-up in the *Miami Herald,* April 12th, 1980, was of great interest to me. I am one of the 15,000 people in the country that suffered with that rare and agonizing interstitial cystitis (Hunner's ulcer of the bladder) for fourteen years.

Praying for a miracle, all those years, I had the good fortune to contact Dr. Robert Hoffberger and his associates, Drs. Fuchs, Rappel and Hoffberger, Urologists, Hollywood, Fla. 33023.

I became their patient in 1978. It was March 1979, Dr. Hoffberger started to treat me with DMSO. First signs of some relief became evident in September 1979. I steadily improved so that treatments were necessary at six week intervals, whereas, in the past, I was getting treatments at two or three week intervals.

As I stated, I had chronic interstitial cystitis for a period of fourteen years. This condition was diagnosed by urologists in the Philadelphia area following cystoscopic examinations. This condition is characterized by a chronic inflammatory process with resultant adhesion formation, and contracture of the bladder. The disease causes constant severe pain so one is immobilized for the greater part of each day.

My life now is changed. I can walk, I can shop and I can go places. I am free of pain and I am very grateful to Dr. Stanley Jacob for this medication.

Finally, I wish to state that my doctors have seen improvements and healing of the ulcer following cystoscopic examination.

The osteopathic physicians, genito-urinary specialists that treated me accepted my Medicare payments *only.*

In addition to the healing of the bladder through use of DMSO, I can also report the relief of pains that I had in the knuckles of both hands. This was diagnosed as arthritis by a physician.

I have written this letter to you knowing your concern for humanity, so that you will use your influence in promoting DMSO.

Sincerely yours,

FRANCES WEERTZEL.

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GRESHAM, OREG., *April 16, 1980.*

Hon. CLAUDE PEPPER,
House Select Committee on Aging,
Washington, D.C.

DEAR SIR: In March, Dr. Jacob from University of Oregon was on 60 Minutes on T.V. to talk about D.M.S.O. I was very much interested as he had been giving it to me since January for osteoarthritis.

It is definitely helping people. They come from New Jersey, Tx. Wash. and seek help. This is a research project that Dr. Jacob is dedicated to. To see the people standing in the halls waiting for to see him would make you realize how dedicated a man he is.

Your name was mentioned in the paper after the T.V. talk. And I remember you well as we were living in Jax., Fla. then, and Jim Wilson, quadruple amputee and my daughter were married there in 1950. Jim spoke so highly of you at that time.

I only wish the Government or American Medical Assn. would approve of this medicine. Arthritis can hit anyone and so this will help all and not just a select few. I can vouch for this. It's cheap, no after affects. To grow old we all must do, and, so to grow old and not fall apart at the seams, we oldsters are asking for help.

Thanking you, I am

Mrs. W. L. SHARPE.

SELAH, WASH., *April 16, 1980.*

Hon. CLAUDE PEPPER,
House Office Building,
Washington, D.C.

We are writing to you and asking you to please push for the procedure it will take to make DMSO legal in all States as well as in our State of Washington. We have known of the relief it can give for pain in arthritis for over 30 years. Also, we are witnessing the recovery of the paralyzed body of Mike Taylor of Edmonds, Wash. He is the son of my brother Lyle G. Taylor. I get great relief of pain with DMSO for insect stings which is great for me; as I am so allergic to so many things. We are praying for the release of this drug for all human beings.

Sincerely,

EDITH T. and JIM W. JOHNSTON.

FALLS CITY, OKLA., *April 16, 1980.*

DEAR HON. CLAUDE PEPPER: Please vote yes on bill H.R. 5851. I understand this bill would allow emergency vehicles to carry and use DMSO. I am in a wheelchair after a logging accident, and believe I wouldn't be if the paramedics could of used it on me then. Using it topically at home the last three weeks has proven to me it works. My left leg has shown muscle return and I can lift it three to four inches. The doctors said my legs would be paralyzed for the rest of my life. So please vote yes. Thank you.

Sincerely,

CHARLES J. GROSS.

PUEBLO, COLO., *April 16, 1980.*

DEAR REPRESENTATIVE PEPPER: (I) myself became interested in 1969 when I was becoming concerned about certain symptoms which were finally developing from a broken neck in 1937. (I damaged the fifth cervical, and the fourth and sixth cervicals were also involved).

I flew to Portland, Oregon where I met Dr. Jacob who provided me with DMSO, and I commenced taking it at once. The symptoms and pain were substantially alleviated the first time I took DMSO. I have continued to take DMSO over that period of approximately 11 years—and I have used it for everything from burns to gum trouble.

Moreover, I have personally witnessed what it has done for myriad others in cases of arthritis (although it does not help everyone with this affliction); cuts and bruises; sprains and strains; muscular degeneration; burns; and I am sure that I am forgetting a number of other afflictions dramatically helped by DMSO during the last decade.

(I)t has been extremely frustrating that the efforts of thousands of people—even with a sweet tiger like Stanley Jacob spearheading the attack—that the FDA won't

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budge on a drug that they admit is non-toxic. And their excuses are very lame. (Had not it been for a man like Stanley Jacob, who would not give up when threatened with jail, DMSO would have disappeared long ago. Moreover, his pleasant personality is a quality that is rare in a man who who is so determined and who is such a fighter).

But without a Claude Pepper, even Dr. Jacob—and all we others—will not be able to get the job done.

You can be sure we are behind you, and we shall be grateful for your efforts.

Thanks again,

MOREY BERNSTEIN.

FRESNO, CALIF., *April 17, 1980.*

Hon. CLAUDE PEPPER,
House Select Committee on Aging,
U.S. House of Representatives, Washington, D.C.

HON. CLAUDE PEPPER SIR: I am writing to tell you how much I appreciate the fact your committee is studying the merits of DMSO. I do hope you will see fit to place it back on the market.

I am a Scleroderma patient and used DMSO for a year on the hardened skin on my fingers. I regained much of mobility of my hands.

My doctor had wanted me to use DMSO on my fingers several years before I did and before the skin on my fingers became so hard, but I didn't know where to get the medicine.

DMSO would really help Scleroderma victims. Thank you.

Sincerely,

Mrs. DOROTHY JOHNSTON.

CLATSKANIE, OREG., *April 18, 1980.*

Hon. CLAUDE PEPPER,
Chairman, House Select Committee on Aging,
Washington, D.C.

DEAR SIR: Regarding the drug DMSO it is my opinion that if this drug was legalized it would be a blessing to millions of our elderly citizens living on small pensions. I am a pensioner myself who has suffered in the past from severe pain in my knees, elbows and shoulders. The use of DMSO on these joints has definitely relieved the pain, so much so that I feel that DMSO is well worth the $20. a pint I paid to get it on the black market.

Many of my elderly friends are also using DMSO for stiffness in their hands and various aches and pains. It has helped them all and none have complained of any bad side effects.

The A.M.A. and the drug industry have only one reason for wanting to keep DMSO from the public. That one reason is pure greed. The doctors and the drug industry know if DMSO is legalized they will lose millions and millions of dollars now being paid by elderly citizens in pain for more expensive forms of treatment which will not give them the relief from their pain that DMSO will. The doctors and the drug industry in this country should hang their heads in shame for placing their obsessive love for money above the needs of the elderly and poor who must live with pain each day because they cannot afford to do otherwise.

Clatsop County, Oregon, where I live has long been noted for its slow growth and limited economy. Many people here are just scraping by and having to make every cent count. These people would not be paying $20. a pint for DMSO if it didn't help them. And if DMSO is harmful to humans why is it legal in so many other countries?

DMSO should be legalized now without any further delay by special interests. They have had over 10 years to test this drug and I am sure they would like to stall for another 10 if they could get away with it. I figure its up to you to see that they don't. Thank you.

Respectfully yours,

DOUGLAS G. BURNS.

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SPRING, TEX., *April 21, 1980.*

M. MARA BLAT,
c/o The Star, New York, N.Y.

DEAR MARA: Just completed reading your Article on Arthritis wherein Dr. Stanley Jacob of Oregon tells part of his story on the fight to get DMSO legalized.

I too have a great interest in the fight to get DMSO approved. You see DMSO can be mixed with so many other drugs to enhance their effectiveness because it carries it thru the skin and flesh so easily. In my particular case DMSO was mixed with a Dye called Haematoxylon, another cheap byproduct of wood, and injected into my veins diluted with regular 5 percent dextrose water every other day. Also I drank it every morning before breakfast. It Cured my Lympho Sarcoma Cancer in less than eighteen months.

For what its worth I would like to tell you my story if I might indulge a little of your time. In April 1974 I realized Hemorrhaging Blood was a bad sign and went to see my Exxon Company Doctor, C. Hunter Montgomery. Upon examination he found I had the worst kind of Cancer in the Colon. We decided on and made arrangements with one Dr. Wade Harris at the Herman Prof. Bldg in Houston. My wife called Dr. Tucker and implored him to treat me. He advised to let Dr. Harris take out as much as possible and we would talk later. In less than a week of Xrays and preparation Dr. Wade Harris removed appx thirteen inches of my Colon and its spread to the Lymph Nodes, cutting as far as possible. He advised I take Chemotherapy for it was only a matter of a few months it would occur somewhere else. He also said his wife was just a month ahead of me with the same identical condition. Well I thanked him and went home Saturday morning. Then the next Monday morning my wife and I called on Dr. Tucker and after a lot of hard persuasion he agreed to give me his treatment on an experimental basis. A dying man can make a pretty good argument to keep on living.

Within six weeks Dr. Harris's wife was dead from taking chemotherapy and I was back at work downtown Houston at the Exxon Building and taking treatments every other day at the Doctor's office. No nausea or any of the symptoms usually accompanied with chemotherapy. I also drank appx. 3/4 cc of the Haematoxylon—DMSO mixed with appx 2 oz. of 5 percent dextrose water before breakfast every morning. After appx eighteen months my CEA tests were far below normal and Dr. Tucker dismissed me as cured, but I was to come by for a check up every thirty days. Now we make a check every three or four months and it is always below normal. The Doctors batting average was now running above 85 percent cure.

While I had been taking treatments from Dr. Tucker I met many of his patients who came by for check ups that he had cured. You can imagine how excited I became over this treatment. I wanted to do something so everybody with cancer could get this drug. I preached it to my friends and acquaintenances but alas when one would mention it to their personal physicians, they wouldn't touch it, especially if it wasn't approved for general use, the hospitals would not let them use it even if they wanted to. I started writing to Congressmen, would get a Thank You letter with a Rubber Stamp signature. Even when Hubert Humphrey was dying I wrote him a letter, but back came another Thank You with Hubert's rubber stamp signature.

Next I wrote Jimmy Carter, thinking someone in the White House might see the political possibilities and pass it on to him. But no, it was side tracked over to the FDA. Excitement, the answer did have a real signature, "Harold Davis" Bureau of Drugs (HFD—35). It was the nice Thank You for concern but we have to protect the people from quackery etc. He even sent me a brochure by Dr's Tucker and A. Carrizo, the same as I am enclosing for you that Dr. Tucker gave me.

Then first part of March 1978 a group of Doctors from New York City called and wanted Dr. Tucker to come and bring his medicine and show them how to use etc. Dr. Tucker called me and asked if I would accompany him and tell my story, to which I replied, "Anytime, anywhere to further our cause."

Before getting off the ground Dr. Tucker received a call from Dr. Pani, HEW Rockville, Md. to please come by there on way to New York and bring him up to date. Dr. Tucker had numerous records of cures, X-rays and slides to show, and when they came to my Record, Dr. Pani asked "How long did this one last, three months?" Dr. Tucker replied "He is sitting down in the lobby." Dr. Pani said "I want to see this dead man." They came down and I told my story. Then Dr. Pani said we would be hearing from him soon. He also mentioned being in contact with Dr. Jacob of Oregon, that he was monitoring use of DMSO. About one week later was when the DMSO was approved for certain ailments of the bladder etc. Use of the Haematoxylon was not approved.

The doctor and I went on to New York. We met several doctors doing cancer research, we showed the X-rays, slides etc. We then flew back to Houston with our

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hopes higher than ever thinking some one of the group would help prove its use. To date very little communication had been forthcoming. Only thing word did come back from Rockville, Md. (FDA) "We need more research." Maybe a sizable investment in a research firm might be helpful. Well there goes the "politics," fighting the lobbyists etc. What can one do while the Shah of Iran and others like him are dying and there is a specific here to cure their lymposarcoma cancers? Who to turn to, someone like you Mara, someone who can find out the truth and spread it out to the public and loop around the bureaucrats and politicians. Ask Dr. Jacob of Oregon, he is well acquainted with Dr. Tucker and his work. In fact it was Dr. Jacob who called Dr. Tucker a few days before Mike Wallace on "60 Minutes" C.B.S. put show about DMSO several weeks ago. Needless to tell you how much suffering and misery this drug would eliminate, save thousands of lives and millions of dollars each year.

The reason I came to know about Dr. Tucker and his treatment was that several years ago on Channel 2 television in Houston there appeared a three hour long show and commentary by Ron Stone telling of Dr. Tucker's discovery and long battle to get it approved to no avail. I thought if ever I or my wife ever get cancer, Dr. Tucker is my man. It was about two years later before discovering I had cancer. Once that the good doctor agreed to take me on I never had another worry or doubt about getting completely cured. Never an ache nor pain, the DMSO took care of that.

Well Mara I won't bother or bore you with all the stories of encounters I have had, stories of cures and stories of people that started the treatment too late but died without pain, thanks to the DMSO. I just wanted you to know my story where the DMSO used in conjunction with haematoxylon, the enclosed brochure will give the details. If I can further this cause, Dr. Tucker and I would be willing to go anywhere, anytime to bring this treatment and I will tell my story. I am 62 years old and a retiree from the Exxon Company. Their chief physician is Dr. Leone who would be glad to vouch for me and my case.

In case you wish to confer with Dr. Tucker, his address is 7000 Fannin Street, Suite 700, Houston, Texas, 77030. Telephone 713-795-5644.

Sincerely yours,

J. B. FLOYD.

Keep up the good fight, sir.
CC: Hon. CLAUDE PEPPER

J.B.F.

LONGVIEW, WASH., *April 22, 1980.*

Hon. CLAUDE PEPPER,
U.S. House of Representatives,
Washington, D.C.

DEAR SIR: I am writing you in regard to the controversial drug DMSO.

With its successful results in arthritis, paralysis, mental retardation and other maladies without apparent side effects I feel it should be made available and at a price also that everyone can afford.

I'm sure the large pharmaceutical companies will fight it tooth and nail as they have Dr. Georges burn medicine.

Why can't the little guy get a break now and then instead of the big conglomerates, as always.

I myself had DMSO prescribed for me by a local ophthamologist working with Dr. Jacobs, to combat macular degeneration.

My eyesight was failing rapidly and we are sure that was stopped and the sight was somewhat improved.

This took place at least seven years ago and there has been no side effects thus far.

Please give this your sincere and immediate attention so the many afflicted with arthritis especially can use it and get relief.

Sincerely,

EVELYN HAMER.

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RITCH & GRAVES,
ATTORNEYS AT LAW,
Gainesville, Fla., April 24, 1980.

Hon. CLAUDE PEPPER,
2239 Rayburn House Office Building,
Washington, D.C.

DEAR REPRESENTATIVE PEPPER: I have noted with interest your investigation into the FDA position regarding Dimethyl Sulfoxide. Therefore, I am writing this letter to attest to DMSO's miracle abilities.

Recently, a veterinarian prescribed DMSO for my German Shepherd, who has arthritis. The veterinarian advised me that the drug was approved for use by horses only, but that due to the apparent inability of other prescription medication to aid my Shepherd in her plight, he was willing to try DMSO. Inasmuch as I have disc problems, I decided to try DMSO on my back. In a matter of minutes, for the first time in 18 months, I was not in pain. I have no way of knowing how long the relief will last, but at the time I am dictating this letter, it has been over 15 hours.

I sincerely hope that you and your select committee on aging will be able to fully explore DMSO and its use. It would be my sincere hope, after experimenting with the drug myself, that DMSO be made available to all people who need it for relief. The Federal Drug Administration, in my opinion, has taken a dim view of something that works strictly because no one can explain why it works.

Keep up the good work.

Cordially yours,

R. FRANKLIN RITCH.

PRINEVILLE, OREG., *April 24, 1980.*

Representative CLAUDE PEPPER,
House Office Building,
Washington, D.C.

DEAR MR. PEPPER: I have been contacted by the Independent Citizens Research Foundation for the Study of Degenerative Disease, Inc., re. the use of DMSO.

I feel that I am quite qualified to comment about DMSO because I have known about it and have worked on many experimental uses for it since it's discovery. In fact, a neighbor of ours was one of the ones that first "stumbled" onto its first unusual effects at Crown Zellerbach's mill at Camas, Washington many years ago.

I am a Registered Nurse and worked for many years with Dr. Rosenbaum at Holliday Park Hospital and Dr. Jacob from the University of Oregon Medical School in Portland, Oregon in many of their first experimental cases.

It would take pages for me to relate the marvelous effects I have seen from the use of DMSO, especially in bursitis and in every stage of arthritis. One would have to be blind or insensitive to human suffering to deprive those patients from the relief they get from the use of DMSO.

My husband is registered at the University of Oregon Medical School to obtain and use DMSO on an experimental basis and he finds DMSO invaluable for the immediate relief and cure of herpes sinplex which he occasionally gets on his lips and across his nose. No other medication has been so effective.

I well remember when the first article re DMSO came out in "Northwest Medicine", a publication for Northwest doctors. Because it scooped the Journal for the AMA it was instantly played down by the AMA and a bitter battle ensued for many years. I really believe that was when the battle lines were drawn and many of the doctors were too stubborn to admit that they could have been wrong.

I had a nephew who suffered severe 2nd and 3rd degree burns on his face and neck from a motorcycle accident. His doctor used DMSO in his treatment and, in my 40 plus years of nursing I have never seen a burn heal so rapidly, without a skin-graft and not even a scar.

I believe every one should have the right to choose if they want to receive this medication in their own particular case upon recommendation of their doctor.

I am thoroughly convinced that if the F.D.A. was just half as careful in passing on some medications as they have been on DMSO maybe some of us would be better off. My husband was just recently put on "Corgard" for high blood pressure. This is such a new medication that it isn't even in the new 1980 P.D.R. (Physician's Desk Reference). I'm sure if it had been more thoroughly tested and researched he certainly would have been told of its side effects, such as slow pulse. I caught it when his pulse had dropped to 38 and he stopped taking it. His doctor's remark was that he guessed it must slow the pulse, too.

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I was put on Persantin for a vasodiolator for carotid arteries—after paying $80.00 for a refill of this medication the doctor told me that it had been decided that it was of no effect and that I might as well flush them down the toilet. I personally think the F.D.A. should tend to some of the business at hand and quit feuding over an issue like DMSO which they have to admit is of untold benefit to thousands of people but they are too stubborn to admit it.

Sincerely,

Mrs. DAVID W. EMSLIE.

MIAMI BEACH, FLA., *May 5, 1980.*

DEAR SIR: The recent exposure and controversy of the FDA and DMSO's recognition necessitated writing to you.

Your champion of exemplary causes leads me to believe you will use your good offices in helping convince the FDA of the need and use of DMSO for rheumatism, arthritis, etc.

I cite my testimonial in DMSO's behalf. My X-rays showed an arthritic deterioration at the base of my spine which made it almost impossible to stand or walk, pain could only be alleviated with drugs. Fortunately, I secured and applied DMSO to affected parts. The pain is gone and normality has returned to me and my household.

My peers, senior citizens, inquire where they can obtain this reasonably priced medicine but it is not easily available. Only the FDA can alleviate this shortage and price gouging. Please help!

A faithful constituent,

DAVID T. SWIDLER.

HUMBLE ORTHOPEDIC ASSOCIATES, P.A.,
Humble, Tex., May 30, 1980.

Congressman CLAUDE PEPPER,
Chairman, Select Committee On Aging,
Washington, D.C.

DEAR CONGRESSMAN PEPPER: Thank you very much for the fine support you are giving the medical profession in the House Bill H.R. 7023. I would like for you to know that I, as a practicing orthopedic surgeon and physician of several years in practice, do appreciate your efforts and I furthermore am of the opinion that DMSO has very definite benefit with regard to patient treatment. This is even more imperative that we are able to write this by prescription inasmuch as the side-effects are, for all practical purposes, non-existent.

Again thank you very much for your contribution against this inexorable bureaucracy that is presently interfering with the practice of medicine in this field.

Very truly yours,

MICHAEL A. DELUCA, M.D.

TONAWANDA, N.Y., *June 12, 1980.*

Hon. CLAUDE PEPPER,
2239 Rayburn Building,
Washington, D.C.

DEAR CONGRESSMAN PEPPER: I am writing to give my report on DMSO. I am 55 years old and have had rheumatoid arthritis for 15 years. After doctoring for many years and taking a variety of arthritis medications I found myself getting progressively worse until I was faced with taking cortisone and a wheelchair. This forced me to find an alternative treatment, DMSO.

After taking DMSO for 1½ years I have suffered no side effects and I am 75% better—no cortisone and no wheelchair. I will continue to take DMSO as long as I am able to afford to travel across the country to get it. Many arthritics have called me and sadly, they are unable to afford to travel for it. They must continue to take ineffective treatments which can cause severe side effects. Cortisone, in fact, has been known to be fatal.

In this beautiful America we can go to the moon while we leave millions of its people suffering needlessly. Even our animals can be treated effectively with DMSO, but not our people. The time has come that we take politics out of medicine. I beg of you to speed the legalization of DMSO throughout this country. Your efforts will be rewarded by knowing that millions of sufferers have been relieved.

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I have enclosed a news letter from the Arthritis Foundation stating that you would like to hear from victims of arthritis quackery and unproven remedies. Referring to DMSO as such would be pre-judging and I would hope a man in your honored position would hold an open mind and collect conclusive evidence before making such a reference to DMSO. If this information is incorrect, I trust you will request a correction.

Our medical establishments have obviously failed us in regards to arthritis. Can our leaders stand by and not take positive action to see justice done?

In hopes that the information you have received during the hearings and in the mail has been sufficient to propose legislation on the use of DMSO, I pray for your accomplishment. Please do not fail us.

Respectfully,

JEAN JONES.

PIEDMONT HOSPITAL AND NURSING HOME,
Piedmont, Ala., June 17, 1980.

Congressman CLAUDE PEPPER,
House of Representatives,
Washington, D.C.

DEAR SIR: Having been made aware of your efforts to make DMSO available to the U.S. Public through physician's prescriptions, I would like to say, thank you. I am a registered pharmacist and I used DMSO to treat my bursitis back in the sixties and have had no long term bad effects from it that I have been able to perceive.

It took three treatments to completely cure the bursitis in my elbow and I have had no recurrence.

I know that you have several people willingly to laud the effectiveness of DMSO and I would like to offer my services as a professional with practical, personal experience in the use of this drug. Should you need my testimony, please, contact me at the address above.

Kindest regards,

JAMES F. ROBINSON.

DOYLESTOWN, PA., *June 7, 1980.*

Hon. CLAUDE A. PEPPER,
Chairman, House Select Committee on Aging,
U.S. House of Representatives, Washington, D.C.

DEAR REPRESENTATIVE PEPPER: In the recent SIF newsletter, I read of your concern with the FDA's refusal to release potentially inexpensive drugs, such as DMSO. It is of DMSO and Scleroderma that I write you today.

Fifteen years ago this month, I was unable to participate in my college roommate's wedding in New York due to a severe sprained ankle, complicated with bone bruises and torn ligaments. I had been on crutches for two weeks, my foot so swollen that the slightest attempt to put any pressure on it brought excruciating pain.

A young Doctor named David Bragg was boarding with the family and associated with Columbia Presbyterian Hospital. He took an unusual interest in my foot and asked if I would be an experimental patient for a "wonder drug" which he was studying. I recall he was tremendously excited upon applying this very ordinary looking liquid and informed me I would sense a garlic taste within seconds. All who were present watched in utter amazement as the swelling subsided and the Doctor asked me to stand and try to walk! Surely I thought he was joking, but I not only stood, I ran around the room! After three applications of DMSO, my foot was healed!

The excitement over this "wonder drug" was contagious as he recounted numerous stories of healings and remarkable findings in all sorts of clinical tests cases.

Upon my return home and throughout 1965, I exhalted DMSO, though my story was received by many with much skepticism. I lost touch with any word of DMSO, and had not heard its name again until recent years.

In August 1974, my mother was misdiagnosed as having rheumatoid arthritis. In three months, she went from a perfectly healthy, vivacious, 58 year old woman, to a helpless cripple, ridden with pain. She worsened, her major organs all ceased to function, and she was confined to a kidney machine. In October we were told she had systemic scleroderma, a rare disease which few had heard of, much less knew much about.

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In January, six months after the onset of this hideous disease, my mother and best friend died.

Four years ago, I became aware of the DMSO controversy through Arkie Barlet's herculean efforts with the Scleroderma International Foundation and I was once again excited. But that excitement has been replaced with frustration and anger. I am repulsed at the thought of FDA bureaucrats and the devious motives behind their refusal to release these low-cost drugs. I am ashamed to think that the "Almighty Dollar" takes precedence over alleviating pain, suffering, and humiliation.

I am sure that while DMSO could not have saved my mother, it could and would have helped alleviate much of the crippling pain she suffered.

I know it works, and I urge you and your committee to continue your fight for the legalization of DMSO and similar superior combinations.

Sincerely,

SUSAN L. HUGHES.

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